CITATION: Apotex Inc. v. Abbott Laboratories Limited, 2013 ONSC 356
COURT FILE NO.: CV-09-391938
DATE: 20130115

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:	
APOTEX INC.	Daniel Cohen, for Apotex Inc.
Plaintiff/Respondent	
- and -	
ABBOTT LABORATORIES, LIMITED, TAKEDA PHARMACEUTICALS COMPANY LIMITED, and TAKEDA PHARMACEUTICALS AMERICA, INC.	Steven Mason and Fiona Legere, for Abbott Laboratories Limited Christopher Van Barr, for Takeda Pharmaceuticals Company Limited and Takeda Pharmaceuticals America Inc.
Defendants/Moving Parties	
	HEARD: October 29, 2012, at Toronto, Ontario

Michael G. Quigley J.

Reasons For Judgment

Introduction

[1] This case is about the extent to which a generic pharmaceutical company can obtain an equitable damages remedy from this court for an alleged violation of the federal legislative regime relating to patented pharmaceuticals – when the exact remedy sought has already been denied by the Federal Court and the Federal Court of Appeal.

[2] In this case, Apotex Inc. claims damages against Abbott Laboratories Limited and Takeda Pharmaceuticals Company Limited based on unjust enrichment. On this motion, Abbott and Takeda seek an order for partial summary judgment against Apotex under Rule 20 of the *Rules of Civil Procedure*.[1] They ask the court to dismiss Apotex's claim for disgorgement of their revenues or profits from sales of their patented medicine PREVACID®, known generically as Lansoprazole.

[3] Lansoprazole is a medication that slows or prevents the production of acid within the stomach. As such, it is used to treat stomach and intestinal ulcers, and gastro-esophageal reflux disease. It is also used in combination with antibiotics to treat and eradicate the *H. pylori* bacteria, which is a major cause of intestinal ulcers. Its commercial value lies in its ability to treat and reduce the risk of gastric ulcers caused by the now widespread consumption of pain relievers known as non-steroidal anti-inflammatory drugs, such as Advil, Motrin, Ibuprofen, Naproxen and Celebrex amongst others.

[4] These litigants know each other well. They have been regular opposing parties in the "drug wars" that have gone on in Canadian courts since 1993. That was when our patent laws were changed to bring Canada into compliance with its international obligations. In particular, Canada fundamentally changed its pharmaceutical patent protection and market sharing policies. It repealed "compulsory licensing" and moved to the present system that respects the 20 year patent monopoly enjoyed by innovator pharmaceutical companies, subject to the "early working exception" and "stockpiling exception" for patent infringements by generic manufacturers.

[5] Years of litigation have ensued between the innovator pharmaceutical companies, like Abbott, Takeda, and others companies such as Eli Lilly and Pfizer, and the so-called generics, like Apotex, Novopharm and Teva. The innovator companies are multinational companies that claim to spend enormous amounts of money on research and development of patented

[1] R.R.O. 1990, Reg. 194.

pharmaceuticals and seek to recover these expenses from patent protected sales of those drugs. But the generics are also very significant companies with international reach and influence. They earn enormous amounts of money by focusing on the production and sale of lower cost generic equivalents of the brand name pharmaceuticals developed by the innovator companies. In Canada, the competition waged between these market participants focuses largely on the legislative and regulatory regime first enacted by Parliament in 1993 and since amended in a manner that is important to this case.

[6] In a nutshell, Abbott and Takeda ask this court to dismiss Apotex's claim for disgorgement of profits they earned *after* they and Apotex *agreed* to settle the Lansoprazole patent litigation. The parties had agreed on a settlement of future damages, but now that agreement has fallen apart.

[7] This is the first action commenced by Apotex in the Superior Court of this, or any, province in which it seeks the disgorgement of the innovators' profits based on unjust enrichment. It has come to this court rather than continuing to pursue the contest in Federal Court. In spite of an agreement between the parties that appears to limit Apotex's damages to those contemplated under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*[2] (*NOC Regulations*), and appears to limit its right to sue, Apotex claims to be subject to no such limitations.

[8] Apotex claims that the laws of this province permit it to pursue the disgorgement remedy regardless of the plain fact that the Federal Court of Appeal has unanimously rejected this position with regard to an almost identical piece of litigation to this one, in a case brought by Apotex where the Supreme Court of Canada has denied leave to appeal.

[9] It is my conclusion and I have found that this is precisely the kind of case that can and ought to be resolved by summary judgment under our Court of Appeal's direction as set out in its decision in *Combined Air Mechanical Services Inc. v. Flesch*[3] (*Combined Air*). There is no need for further evidence here to deal with the limited questions that are asked on this partial summary judgment motion or to provide a full appreciation of this case.

[10] I am satisfied that there is no genuine issue that requires a trial in this case. In my view, Abbott and Takeda are entitled to the partial summary judgment they seek. The motions are granted. The claim brought by Apotex for disgorgement of the defendants' profits, based on unjust enrichment outside of the parameters of s. 8 of the *NOC Regulations*, is dismissed.

---

[2] SOR/93-133.

[3] 2011 ONCA 764, 108 O.R. (3d) 1.

The Legislative Framework

The *Patented Medicines (Notice of Compliance) Regulations*

[11] Before any new drug may be sold in Canada, the Canadian *Food and Drug Regulations*[4] require that the vendor obtain a notice of compliance (NOC) from the Minister of Health. The NOC may only be issued where four requirements are met, only two of which are relevant here.

[12] An innovator manufacturer who has invented a new pharmaceutical may only sell that drug where it has filed a submission related to the new drug that is satisfactory to the Minister[5] and where the Minister has issued a notice of compliance for that drug. In the case of a generic manufacturer, just as in the case of the innovator, the new drug may only be sold if the generic manufacturer also obtains a NOC from the Minister, issued under one of two other provisions of the regulations.[6]

[13] This notice of compliance system originated in 1993 when Parliament changed Canadian law relative to the protection of pharmaceutical patents. Before that time, a regime was in place for many years that involved so-called "compulsory licensing". Under that system, the innovators were compelled to issue manufacturing licenses to generic manufacturers in Canada. Government policy at that time clearly favoured health-care cost savings over the protection of the patent rights of the innovator.

[14] In 1993, Parliament reversed that policy. It repealed the compulsory license provisions of the *Patent Act*,[7] and all compulsory licenses were extinguished. These changes were precipitated by international obligations that Canada had accepted respecting intellectual property rights,[8] but there was also concern that the existing compulsory licensing might be legally incompatible with the obligations Canada had just recently taken on under the *North American Free Trade Agreement*[9] signed at the end of 1992.[10]

---

[4] C.R.C., c. 870, as last amended to September 20, 2012.
[5] Ibid., s. C.08.002 (1)(a) and (b).
[6] Ibid., ss. C.08.004 or C.087.004.01.
[7] R.S.C., 1985, c. P-4.
[8] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 U.N.T.S. 299 33 I.L.M. 1197 (entered into force 1 January 1995).
[9] 17 December 1992, Can. T.S. 1994 No. 2. 32 I.L.M. 289 (entered into force 1 January 1994).
[10] See: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533.

[15] When Parliament changed that earlier policy and signalled its intention to respect the 20-year patent monopoly enjoyed by the innovator pharmaceutical companies, it also determined that a balance was necessary. To achieve that balance, generic manufacturers would be permitted to enter the marketplace immediately after the expiry of the patent, rather than having to wait an additional two years, and generic manufacturers would be permitted to prepare for that market entry date without being considered to have infringed a patent. That goal was achieved through the enactment of the so-called "early working exception" and "stockpiling exception" arrangements. The system is described at paragraph 11 of the *Bristol-Myers* decision:

> However, having agreed to respect the 20-year monopoly granted by patents, Parliament wished to facilitate the entry of competition immediately thereafter. It acted to eliminate the usual regulatory lag of two years or more after expiry of a patent for the generic manufacturer to do the work necessary to obtain a NOC. Parliament did so by introducing an exemption from the owner's patent rights under which the generic manufacturers could work the patented invention within the 20-year period ("the early working exception") to the extent necessary to obtain at NOC at the time the patent(s) expired (s. 55.2 (1)) and to "stockpile" generic product towards the end of the 20-year period to await lawful market entry (s. 55.2 (2)). In order to prevent abuse of the "early working" and "stockpiling" exceptions to patent protection, the government enacted the *NOC Regulations* that are at issue in this appeal.

[16] Prior to the promulgation of the *NOC Regulations* on March 12, 1993, a patentee wishing to challenge the entry of the generic product on the market was required to commence an ordinary action for infringement of patent and to seek an interlocutory injunction to restrain the generic. It was required to satisfy the traditional law respecting injunctions and in particular, the three tests relating to: (1) the presence of a serious case; (2) the balance of convenience; and, (3) damages as an insufficient remedy.

[17] In contrast, the new *NOC Regulations* took a different approach. They established a comprehensive regime designed by Parliament to balance the exceptions to an inventor's patent in favour of a generic manufacturer with the implementation of a summary procedure. That procedure was designed to strengthen the innovator's patent rights, but it was also designed to balance those rights by creating procedures to ensure accelerated market access in favour of the generic manufacturers.

[18] The *NOC Regulations* were enacted under s. 55.2(4) of the *Patent Act*. Their general scheme was to create a "Patent Register", maintained by the Minister of Health.[11] An innovator pharmaceutical company would be entitled to list certain patents on that Register that it claimed were relevant to its various drug submissions.[12] If a generic company filed an Abbreviated New Drug Submission seeking approval for sale of a copy of a patented drug, it could follow one of two alternative courses of action. It could either wait until the expiry of the listed patents, or it

---

[11] *NOC Regulations*, s. 3.
[12] Ibid., s. 4.

could challenge one or more of the those patents by way of a "Notice of Allegation" (NOA) on the basis either that the patents were invalid, or not infringed, or both.[13]

[19] Upon receipt of a NOA from a generic, the innovator also had alternative choices. It could simply do nothing, in which case a NOC would be issued. Alternatively, it could challenge the generic's allegation by commencing an application under s. 6 of the *NOC Regulations* to prohibit the Minister from issuing an NOC to the generic until the expiry of the patent in question (an "NOC proceeding").

[20] It is a unique feature of the *NOC Regulations* that the mere commencement of a NOC proceeding by an innovator triggers an automatic statutory stay that prohibits the Minister from granting an NOC to the generic manufacturer for 24 months, unless the NOC proceeding is disposed of earlier.[14] Not surprisingly, generic manufacturers complain that this is the equivalent of granting an automatic interlocutory injunction without being required to meet any of the usual threshold tests. It is true that the Supreme Court of Canada referred to this process and the remedy available to patentees as "draconian" in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*,[15] but it nevertheless confirmed the legality of that system and the complete nature of the regulatory code established by the *NOC Regulations*.

[21] Against this background, the remedies take on enormous significance, as they are available to: (i) prevent abuse of this procedure; or, (ii) compensate a generic for damage suffered for a delayed issuance of a NOC and delayed market access. Those remedies are set out in s. 8 of the *NOC Regulations*, and it is those remedies that are the central focus of this case.

[22] Importantly, however, the 24-month stay does *not* freeze all Ministerial action. The Minister must still proceed with its review of the generic manufacturer's drug submission. Once that review is complete, provided that the Minister is satisfied that the other conditions of the *Food and Drug Act Regulations* have been met, the generic will be placed on "patent hold" until the disposition of the ongoing NOC proceedings.

[23] If the innovator wins the NOC proceeding, the Minister is prohibited from issuing the NOC until the patent expires. If the generic manufacturer wins the NOC proceeding, then, provided that the generic's drug submission has otherwise been approved by the Minister and is on "patent hold", a NOC will immediately be issued, permitting the generic to enter the marketplace. The patent hold is itself significant to the remedies for being denied market access during the compulsory stay period. This is because those remedies only apply once a generic could otherwise access the market, and access to the market is only possible once Ministerial approval is received for the generic manufacturers' drug submission.

[24] Given the significant economic stakes to both innovator pharmaceutical companies and generic manufacturers, it is also not surprising that this procedure, these regulations, and the remedies available under the regulations have been the subject of an inordinate, overwhelming amount of patent related litigation. Indeed, hundreds of NOC proceedings have been heard and

---

[13] Ibid., ss. 5(b)(ii), (iii) or (iv).
[14] Ibid., s. 7.
[15] [1998] 2 S.C.R.193, at para. 33.

determined by the Federal Court and Federal Court of Appeal since the introduction of the *NOC Regulations* in 1993 and many other cases have been filed in the Federal Court addressing the applicability and operation of the *NOC Regulations*.

[25] However, despite the fact that all Canadian Superior Courts have concurrent jurisdiction with that of the Federal Court under the provisions of the *Federal Courts Act*,[16] other than on exclusive jurisdiction heads of subject, I was advised by counsel that to their best knowledge, no NOC proceeding has ever been filed or determined by this court. This is the first.

Section 8 Remedies

[26] Section 8 of the *NOC Regulations* provides the remedy to generic drug manufacturers for being precluded from having access to the marketplace to sell their generic products on a timely basis, owing to their inability to obtain a NOC due to operation of the mandatory two year stay.

[27] As mentioned above, the NOC system is designed to prevent patent infringement against innovator drug manufacturers yet provide for "early working" and "stockpiling" exceptions and s. 8 remedies to level the playing field for generic manufacturers. It is a comprehensive system. What the system is not meant to do, as is made plain from Parliament's description of the balance when it enacted these regulations, is to provide a mechanism that permits innovators to improperly deny access to the marketplace to generic manufacturers.

[28] The nature of that balance and its emphasis on preventing patent infringement has been an important aspect to the approach the courts have taken to the interpretation of this regulatory regime. Given the balance that is intended to be present, as emphasized at para. 192 of *Bristol-Myers*, the Supreme Court emphasized that interpretive caution should be exercised:

> Statutory interpretation is a legal art which needs to be applied very carefully by the courts without losing sight of the underlining principle of such a task. The NOC Regulations purport to maintain a balance between the protection of patentees' rights and the timely market entry of generic competitors. *This Court should not undertake to fill in the alleged gaps or resolve the alleged deficiencies of the legislative and regulatory scheme.* [Emphasis added.][17]

[29] When originally enacted, s. 8 did not read as it does presently. Before 2006, s. 8(4) of the *NOC Regulations* permitted the court to order an innovator pharmaceutical company to compensate a generic manufacturer in respect of a loss for delayed marketplace access by way of an "order for relief by way of damages *or profits* that the circumstances require" (emphasis added).

[30] Even during that time, however, the jurisprudence denied generic drug manufacturers the ability to obtain a disgorgement of revenues earned by innovator drug manufacturers during the

---

[16] R.S.C., 1985, c. F-7.

[17] See also: *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at paras. 14-16, where that balancing framework was again reviewed by the Supreme Court.

statutory period of innovator's exclusive access to the marketplace. The reference in the regulations to "profits" was jurisprudentially limited to refer *only* to the generic manufacturer's lost profits resulting from market exclusion and not to the profits realized by the innovator from its period of exclusive market presence.

[31] The first case to consider the s. 8 damages remedy also involved Apotex as the generic manufacturer seeking to obtain a disgorgement of profits from an innovator, which is interesting but not surprising, given the pervasive presence of Apotex before the courts in patent-related litigation. In *Apotex Inc. v. Merck & Co. Inc.*,[18] however, the Federal Court of Appeal rejected Apotex's claim for disgorgement of Merck's profits even under the former language of the regulation.

[32] The question on appeal was whether Justice Hughes had properly rejected Apotex's contention that it was entitled to compensation by way of a disgorgement of Merck's profits. Apotex relied on what it claimed to be the plain grammatical meaning of the words in s. 8 of the *NOC Regulations*, arguing that Hughes J. had construed the provision too narrowly. It said he failed to recognize that a disgorgement of profits for an alleged wrongful invocation of the stay period was entirely consistent with the object and scheme of the *Patent Act* and those regulations.

[33] The court rejected Apotex's appeal. Justice Noel concluded that "reading down", as opposed to "reading in", was the appropriate and recognized approach to statutory interpretation to the extent that the context indicated that a narrow scope was intended. Hughes J. had correctly concluded that adding the word "lost" in reference to "damages or profits" *narrowed* the scope of the expression and therefore "read down" the provision in a manner that was consistent with the intent of Parliament.

[34] The Federal Court of Appeal also agreed with Hughes J. that, read contextually, the s. 8 "loss", and thus the "compensation" resulting from the operation of the automatic stay, was to be computed by reference to the actual loss suffered by the generic manufacturer by reason of the stay. That is, the compensatory damages should be for the profits that it would have made during the period when it was prevented from going to the market. However, Apotex could not succeed in obtaining disgorgement of the patentees' revenues and its argument that it should be entitled to all the remedies available to a patentee whose patent has been infringed ignored that it was not the holder of the patents.

[35] Rather, the compensation provided under s. 8 was for prejudice *actually suffered* by the generic by reason of the operation of the stay. As such, Noel J.A. continued as follows at paras. 90-91:

> In so holding, I reject Apotex's assertion that the disgorgement of Merck's profit is necessary in order to achieve the balance which underlies section 55.2 of the *Patent Act*. In my view, a measure which compels a first person to place the second person in the position in which

[18] 2009 FCA 187, [2010] 2 F.C.R. 389.

> it would have been, if the operation of the stay had not been triggered, fits well within the contemplated balance.
>
> I therefore conclude that the Federal Court judge came to the correct conclusion when he held that s. 8 of the *PM(NOC) Regulations* does not envisage the disgorgement of a first person's profit.

[36] It is important, however, that Parliament itself decided to amend the regulation even before that judicial interpretation had been given to the previous text of s. 8. It did so evidently in part to exclude the possibility of a patentee's revenues or profits being open to disgorgement claims at the instance of generic manufacturers. In 2006, s. 8 was amended specifically to exclude any reference to "profits".

[37] Moreover, the government issued a Regulation Impact Analysis Statement (RIAS) giving insight into its intention in enacting these amendments.[19] Overall, the RIAS shows the government's policy intent was to restore what it regarded as the original underlying foundation of the *NOC Regulations*, that is, that generic manufacturers were not entitled to access the profits of innovator drug companies.

[38] That particular RIAS acknowledged, by way of background, that the government pharmaceutical patent policy tries to balance effective patent enforcement over new and innovative drugs with the timely market entry of lower-priced generic competitors, and seeks to achieve that balance through the "early working" exception, and the "stockpiling" exception, on the one hand, and the *NOC Regulations* on the other. At page 1511, the RIAS explains further how those two elements are intended to achieve the balance that is claimed to be at the heart of Canadian government policy relating to this issue:

> Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic companies allegation. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

---

[19] SOR/2006-228 to 248 and SI/2006-119 to 224, *Canada Gazette, Part II*, October 18, 2006.

[39] Two paragraphs of the RIAS specifically reference the amendment to remove the word "profits" from s. 8. These paragraphs make it plain that the disgorgement of an innovator's profits is not a remedy that is intended to remain available under the revised language of s. 8, even if it was an available interpretation before amendment:[20]

> Last among the substantial changes proposed by these amendments are refinements to the s. 8 damages provision. The first such change is to further specify the matters the court may take into account when calculating the period of delay for which an innovator may be held liable under that section. The second is to confirm that the Minister cannot be held liable for any delay under that section. The third is to remove the word "profits" from the provision describing the remedies available to a generic manufacturer seeking compensation for any loss arising from that delay.
>
> On this last point, the Government is aware of a number of ongoing s. 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the PM(NOC) Regulations by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovators profits. While reserving comment on the proper interpretation of the term in these cases, which have been shielded from this change by transitional provisions, in light of the proposed tightening of the listing requirements under amended section 4, and of the introduction of the frozen register mechanism under amended section 5, *the government believes that this line of argument should no longer be open to generic companies that invoke s. 8.* [Emphasis added.]

[40] This RIAS does not limit the jurisdiction of this court to interpret the plain meaning of the provisions of s. 8 as amended by Parliament, but certainly the decision by government to specifically comment on the disgorgement of profits issue in that RIAS must be taken as an indication of the intent that lay behind the introduction of the amendment.

[41] Supreme Court of Canada jurisprudence shows that RIAS documents issued by government from time to time as indicative of Parliamentary intent may be used by the court in its interpretation of provisions such as s. 8 as amended, to determine both the purpose and the intended application of a regulation. Further, the use of such documents has also extended across a wide range of interpretive settings.[21]

Background of this litigation and settlement

[42] This is not the first litigation that has focused on the Lansoprazole patent. The history of this litigation and other patent cases closely related to it has been complex, focusing on whether the *NOC Regulations* and s. 8 in particular constitute a complete legislative code and on the

---

[20] Ibid., at page 1521.

[21] See: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, at para. 157, and cases cited there.

likelihood of equitable remedies being available beyond the parameters of that legislative framework.

[43] The Lansoprazole patent, referred to as the '741 patent, was first the subject of a patent infringement action brought by Abbott against Novopharm in 2006. Abbott sought an order under the *NOC Regulations* prohibiting the Minister of Health from issuing a NOC to Novopharm for its generic version of Lansoprazole, until after the expiration of the '741 patent. At that time, Lansoprazole was a known compound. It was used to treat gastric acid secretions. However, the '741 patent was a patent for the use of Lansoprazole as an antibacterial agent to treat and prevent infectious diseases caused by the *H. pylori* bacteria.

[44] Novopharm alleged that it would not infringe the '741 patent because its generic version of the drug would be marketed only for the old uses of Lansoprazole, and not for any new use protected by the '741 patent. Abbott's response was that even if approved for the treatment of conditions *other* than those specified in the claims, physicians would use sales of Novopharm's generic version of Lansoprazole to treat *H. pylori* infections should the Minister issue a notice of compliance.

[45] Moreover, Novopharm's product monograph and marketing strategy were obviously designed to encourage and promote the use of Lansoprazole for the treatment of ulcers caused by *H. pylori*. This was evident from the labelling of its generic Lansoprazole product that advocated a dosage regime that could *only be used* for the treatment of *H. pylori* infections, and that was *incompatible* for the old, allegedly accepted and unprotected use.

[46] Justice von Finckenstein of the Federal Court had no difficulty seeing through to the actual purpose that lay behind Novopharm's NOA. He found in Abbott's favour. He issued a prohibition ordering the Minister not to issue a NOC until the expiry of the '741 patent and the Federal Court of Appeal upheld that decision.

[47] Even though the prior patent for the use of Lansoprazole to treat excess gastric secretions had expired, it was clear to the Court of Appeal that the use actually sought by Novopharm was not for that purpose, but rather for the treatment of ulcers caused by *H. pylori* – the very use protected by the new '741 patent. Consequently, Novopharm's use of the Lansoprazole product would infringe the '741 patent if the Minister issued it a NOC.

[48] There are several points of importance that flow from Abbott having successfully rebuffed Novopharm's claim in that case. The first is that the Minister did not issue a NOC and so Novopharm was not granted permission to manufacture Lansoprazole. Consequently, no s. 8 damages claim could have been instituted by Novopharm against Abbott because Novopharm was not precluded from entering the marketplace by Abbott as it had not yet received a NOC from the Minister permitting it to sell Lansoprazole.

[49] Regardless of that decision against Novopharm, Apotex commenced its own NOA against Abbott and Takeda. It did so relative to *exactly* the same Lansoprazole patents that had been challenged by Novopharm.

[50] Indeed, the Apotex allegations of non-infringement and invalidity of the '741 patent were *virtually identical* to those found not to be justified by the Federal Court in the Novopharm proceeding, and which resulted in the issuance of a Prohibition Order against Novopharm.

[51] The responding NOC proceeding that was commenced by Abbott against Apotex under the *NOC Regulations* was ultimately settled. The last of those NOC proceedings ended on September 11, 2008, when Apotex agreed to respect the '741 patent for most of its remaining life.

[52] The settlement agreement concluded between Abbott, Takeda and Apotex is important to this case. It was reached at a point in time where Justice Phelan had his decision under reserve in the Apotex litigation between these parties. Under its terms, Apotex agreed to stay off the market. Further, it *only* reserved the right to claim damages under s. 8 of the *NOC Regulations*, but nothing else. Apotex also acknowledged in its subsequent damages claim in Federal Court that the agreement specifically permitted it to advance a claim for s. 8 damages in respect of its exclusion from the market for Apo-Lansoprazole capsules from April 1, 2007 to May 1, 2009, and Apotex emphasizes that it was entitled to claim those damages for that exclusion by reason of those *NOC Regulations*. Nothing in that agreement permits Apotex to commence an action for unjust enrichment.

[53] There are other significant aspects to that agreement. Apotex was only prevented from entering the marketplace prior to May 1, 2009, and was restricted to claiming damages for the period from April 1, 2007 to May 1, 2009. It is plain that there was a negotiated reason for this, because while it was agreed that Apotex agreed to stay off the market for an additional eight months from the date the settlement was reached, Abbott and Takeda agreed to permit Apotex to have market access *eight months earlier* than February, 2010, when it would otherwise would have been entitled to start selling Apo-Lansoprazole due to the expiry of the '741 patent. The parties also agreed in paragraph 6 of the agreement that they would not institute further litigation against each other with respect to Lansoprazole.

[54] Thus, as of September 2008, the *NOC Regulations* did not present a bar to Apotex receiving a NOC for Apo-Lansoprazole, *provided* its submission was otherwise in compliance with the *FDA Regulations*. The problem for Apotex was that it was not, as there were other regulatory problems with its submission. As a result, Apotex did not actually receive a NOC for its Apo-Lansoprazole product until June 3, 2009, nine months later.

[55] This delay in NOC is an important fact that explains why Abbott and Takeda say that the Apo-Lansoprazole product was never truly on "patent hold" during their NOC proceedings against Apotex. As a result, it is their position that Apotex never actually had any legal right to make a claim for damages in accordance with the *NOC Regulations*. In any event, Abbott and Takeda assert that Apotex got what it bargained for, namely, access to the marketplace eight months before it otherwise would have been entitled to it, and an additional eight months of s. 8 damages entitlement under the *NOC Regulations*.

[56] Then the course of the litigation took a sharp turn. Apotex discontinued its Federal Court action for damages against Abbott and Takeda on September 1, 2009. By that time, it had commenced this action against these parties in Ontario Superior Court. In addition to the s. 8

damages claimed in the Federal Court, allegedly caused by Abbott and Takeda's initiation of prohibition proceedings against it under the *NOC Regulations*, Apotex now again claims disgorgement of the defendants' revenues relative to Lansoprazole, this time before this court rather than the Federal Court. Specifically, the Apotex amended statement of claim, dated November 25, 2009, as amended to August 17, 2010, claims:

> ...disgorgement of the Defendants revenues, or alternatively profits, generated from sales of their Prevacid® product realized by the defendants as a consequence of: (i) the delay attributable to the Defendants invocation of the Patent Regulations, and/or (ii) the agreement entered into between the Plaintiff and the Defendants made effective September 1998 as described below.[22]

[57] This tortuous and convoluted history, combined with a number of other proceedings discussed below, has led to this summary judgment motion.

Recent legal developments digested

[58] Important developments have taken place in this litigation and in the law that relates to it since this case was commenced in this province, both before and after this summary judgment motion was argued. Each of these developments bear on this summary judgment motion, and so I have provided a brief digest of these decisions to provide context for the analysis that follows.

(i) ***Abbott and Takeda v. Apotex*: the first motion to strike**

[59] The first decision in this case was rendered on a motion to strike Apotex's pleadings under Rules 21 and 25 of the *Rules of Civil Procedure*. It was heard on October 12, 2010, and Justice Whitaker released his decision on December 15, 2010.[23] He concluded that none of the authorities that had been placed before him and relied on by Abbott dealt directly with a claim for unjust enrichment and disgorgement of profits. As a result, in his view, it was neither established law nor plain and obvious that a claim for disgorgement *could* not succeed. At paragraphs 54-55 he stated that:

> As indicated earlier, there is no detailed analysis in support of the complete code theory. I conclude that the defendants' central proposition of law is not "plain and obvious" but is rather "muddy".
>
> It may well be that the theory advanced by Abbott will someday be found to be correct following trial but that is not the test on this motion and this is not that day. It is not plain and obvious that the claims for unjust enrichment and disgorgement are doomed to failure – they should not be struck on that basis.

---

[22] The reference to 1998 is certainly a typographical error since the date of that settlement agreement was September 11, 2008.
[23] 2010 ONSC 6909.

[60] It is noteworthy, relative to the importance Apotex ascribes to this decision and the one that follows it, that Whitaker J. specifically emphasized that he was not deciding or determining any question of law or fact in that proceeding.

(ii) *Abbott and Takeda v. Apotex*: application for leave to appeal

[61] Abbott and Takeda then applied for leave to appeal Justice Whitaker's decision to the Divisional Court. Justice Swinton heard the application on June 21, 2011, and released her decision on July 4, 2011.[24]

[62] To prove unjust enrichment, she noted that a plaintiff must prove an enrichment of the defendants, a corresponding deprivation and the absence of a juristic reason for the enrichment. In her view, however, no case had decided whether the decision of a patent holder to commence an unmeritorious proceeding under the *NOC Regulations* might give rise to a cause of action in unjust enrichment by the generic drug manufacturer. Stated differently, the key question for her was whether there can be a remedy in unjust enrichment, outside of the *NOC Regulations*, if the innovator commences litigation against the generic under the regulations for the sole purpose of keeping the generic out of the marketplace. She concluded that it was not plain and obvious that the *NOC Regulations* constituted a complete code or that an order for compensation based on unjust enrichment would undermine the purpose of the regulation.

[63] In Justice Swinton's opinion, the law on the point was unsettled as to when a statute will provide a juristic reason for enrichment. Moreover, in her view, given the state of the law as it rested at that time, there was nothing improper in Apotex commencing the action for unjust enrichment in the Superior Court of this province, rather than carrying on before the Federal Court. At paragraph 21 she stated as follows:

> In the present case, it is not obvious that the Plaintiff is attempting to do indirectly what it cannot do directly under the statutory scheme. The Federal Court of Appeal decision in *Apotex Inc. v. Merck and Co.*, 2009 FCA 187 at paras. 82–91 determined that s. 8 of the PMNOCR does not give rise to a claim for the profits of the patent holder. It made no determination as to whether a generic manufacturer can claim those profits pursuant to common law and equitable causes of action.

(iii) *Apotex v. Eli Lilly*: the Federal Court of Appeal decision

[64] The Federal Court of Appeal decision in *Apotex v. Eli Lilly Canada Inc.*[25] is central to this motion for summary judgment. It was heard on December 21, 2011, after both the original motion to strike and the leave application had been heard and decided in this case.

[65] Eli Lilly and Nycomed brought proceedings under the *NOC Regulations* against Apotex, but both had been dismissed. Consequently, Apotex sought damages against both companies

---

[24] 2011 ONSC 3988 (Div. Ct.).
[25] 2011 FCA 358.

under s. 8 of the *NOC Regulations*. However the s. 8 damages sought by Apotex in that case, as in this case, were the disgorgement of all profits earned by the innovator companies during the period when Apotex's NOC was withheld. That NOC was allegedly withheld because of a "wrongful invocation" by Eli Lilly and Nycomed of the statutory stay period provided for under the *NOC Regulations*, the same accusation levelled against Abbott and Takeda in this case.

[66] Apotex argued that damages calculated under s. 8 would be inadequate and not representative of its loss because the profits earned by the respondents, due to Apotex's absence from the Canadian marketplace, permitted them to charge higher prices than could have been charged during the same time had Apotex received a NOC from the Minister. Apotex relied upon the Federal Court's equitable jurisdiction under section 20(2) of the *Federal Courts Act*, for its claim for disgorgement of profits.

[67] When the claims came before the prothonotaries of the Federal Court, Prothonotary Milczynski and Prothonotary Tabib struck the paragraphs from Apotex's statements of claim in which it claimed disgorgement of revenues or profits. There were two appeals that followed, heard together but not consolidated, involving Apotex as the appellant. Both raised the same issue – whether those paragraphs seeking damages under s. 8 of the *NOC Regulations* were properly struck. The Federal Court of Appeal confirmed that those pleadings were properly struck and dismissed the Apotex appeal. This core decision is discussed extensively in the analysis that follows.

(iv) *Eli Lilly v. Apotex*: the second motion to strike

[68] The last development before this motion was a motion to strike brought by Eli Lilly six months ago in June 2012.[26] That case, like this one, involved an action commenced by Apotex for damages because the steps taken by Eli Lilly to commence a proceeding for an order prohibiting the Minister from issuing a NOC delayed Apotex's marketing of its generic drug.

[69] Stated simply, while part of the pleading was struck, the main plea of an unjust enrichment based on disgorgement of revenues was permitted to continue. J. Macdonald J. determined that it was not plain and obvious to him that the action commenced by Apotex could not succeed based on principles of unjust enrichment. Having regard to the standard applicable on a Rule 21 motion to strike, paragraph 52 of the statement of claim pleaded material facts that in his view did support the three criteria required for a claim in unjust enrichment, namely, an alleged enrichment of one party, a corresponding deprivation of the other, and the absence of a juristic reason for the enrichment.

[70] Further, in a point of importance to the analysis here, he opined that if the *NOC Regulations* were going to take away the right of Apotex or other generics to obtain relief at common law or equity, then specific wording was required. Paragraph 29 of his reasons reads as follows:

> In my view, pursuant to r. 21.01(1)(b) it is not plain and obvious that the PMNOC Regulations and, in particular, s. 8 thereof limit the claims

---

[26] *Apotex Inc. v. Eli Lilly and Co.*, 2012 ONSC 3808, 111 O.R. (3d) 683.

> which a plaintiff who relies on these regulations may make, so that the Respondent herein is entitled only to the remedies which s. 8 provides and is not entitled to make an equitable unjust enrichment claim. These regulations say nothing about limiting such a plaintiff's rights of recovery. Only explicit statutory language may take away existing rights such as causes of action: see *Rawluk v. Rawluk*, [1990] 1 S.C.R. 70; *Crystalline Investments Ltd. v. Domgroup Ltd.*, 2004 SCC 3, [2004] 1 S.C.R. 60; *Apotex Inc. v. Abbott Laboratories, Ltd.*, 2010 ONSC 6909, at paras. 52 and 53, lv. to app. ref'd, [2011] O.J. No. 3311. For these reasons, the pleading also does not contravene r. 25.11 (b) and (c).

(v) **More recent developments**

[71] Shortly after this motion was heard, two other decisions were rendered, the first by the Supreme Court of Canada in *Teva Canada Ltd. v. Pfizer Canada Inc.*[27] released on November 8, 2012, and the second was a summary judgment motion heard by Justice Zinn of the Federal Court in *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*[28] on October 30, 2012, with his decision also released on November 8, 2012.

[72] I wrote to each of the parties to this litigation on November 27, 2012, while this decision was under reserve, to request that they make brief written submissions to me with regard to the impact, if any, of Justice Zinn's decision in *Apotex v. Pfizer* on this outstanding motion for summary judgment in this proceeding. That decision is discussed further at the end of these reasons relative to whether the Federal Court of Appeal's decision in *Apotex v. Eli Lilly*, above, ought to be followed in this case.

Issues

[73] There are four issues that require resolution here, the last of which has two subparts. They are as follows:

(i) Is the equitable jurisdiction of this court and the Federal Court the same?

(ii) Is this an appropriate case for summary judgment?

(iii) Should this court follow the reasoning of the Federal Court of Appeal?

(iv) Are there juristic reasons for the alleged enrichment of Abbott and Takeda?

(a) Are the NOC Regulations a juristic reason for the enrichment?

(b) Is the settlement agreement a juristic reason for the enrichment?

---

[27] 2012 SCC 60.
[28] 2012 FC 1301.

Is the equitable jurisdiction of this court and the Federal Court the same?

[74] The initial issue that I consider relevant on this motion is jurisdiction. That question is whether this court enjoys the same or broader jurisdiction to grant equitable relief as a provincial Superior Court of record than the Federal Court. Clearly, this court has broader equitable jurisdiction than the Federal Court to the extent that it is a general superior court of record established under s. 96 of the *Constitution Act, 1867*, whereas the Federal Court's jurisdiction is limited to those matters enumerated in the *Federal Courts Act*. But the question here is limited to those subject matters that fall within the concurrent jurisdiction of *both* courts. On those subject matters is the equitable jurisdiction of both courts the same, even if resting on differing legal foundations?

[75] The issue of jurisdiction needs to be addressed because Apotex now claims exactly the same equitable disgorgement remedy before this court that it has been denied relative to other patentees by the Federal Court. Thus, it is important to address the comparative jurisdiction of this court and the Federal Court to award equitable relief as it relates to the patent-based subject matter of the claim to determine if the jurisdiction of this court exceeds that of the Federal Court. That question, in turn, affects the extent to which a decision of the Federal Court of Appeal should be considered to be binding on this court, just as it would be on the Federal Court, even though I acknowledge it is not binding based on *stare decisis*.

[76] The point is also important because evidently this is the first NOC case that has been commenced with respect to a patent in a Superior Court in Canada.

[77] The answer, however, is a simple one. It is to be found in s. 3 of the *Federal Courts Act*. That provision constitutes the Federal Court as a court of equity. As such, the Federal Court has the jurisdiction of a court of equity and may exercise all the powers and enforce all of the remedies available to a court of equity, such as this court. Even though the Federal Court is a creature of statute and not a court of general jurisdiction, it has this equitable jurisdiction *provided* that the subject-matter is otherwise within its jurisdiction and where equitable principles are otherwise applicable to the issue.

[78] Thus, when the Federal Court is dealing with a subject-matter within its exclusive jurisdiction, or a matter on which it has concurrent jurisdiction, it has the same discretion to award equitable relief as the Superior Court. Put differently, equitable jurisdiction involving subject-matter that is within the exclusive or concurrent jurisdiction of the Federal Court is not narrower than that of the Superior Court. Looked at from the other perspective, while this court has no jurisdiction on those particular subjects that are within the exclusive jurisdiction of the Federal Court, such as the *validity* of a patent, it also does not have a broader equitable jurisdiction than the Federal Court with respect to those heads of subject on which the jurisdiction of the two courts is *concurrent*. The awarding of damages for patent infringement or damages for alleged abuse by a patentee of the automatic stay provisions of the *NOC Regulations* are both examples of such concurrent jurisdiction.

[79] The relevant sections of the *Federal Courts Act* are ss. 3 and 20. They provide as follows:

> 3. The court of law, equity and admiralty in and for Canada now existing under the name of the Federal Court of Canada is hereby continued as an additional court for the better administration of the laws of Canada and shall continue to be a superior court of record having civil and criminal jurisdiction.
>
> 20(1) The Trial Division has *exclusive* original jurisdiction, between subject and subject as well as otherwise,
>
> (a) in all cases of conflicting applications for any patent of invention, or for the registration of any copyright, trade-mark or industrial design, and
> (b) in all cases in which it is sought to impeach or annul any patent of invention, or to have any entry in any register of copyrights, trade-marks or industrial designs made, expunged, varied or rectified.
>
> (2) The Trial Division has *concurrent* jurisdiction in all cases, other than those mentioned in subsection (1), in which a remedy is sought *under the authority of any Act of Parliament or at law or in equity respecting any patent of invention*, copyright, trade-mark or industrial design. [Emphasis added.]

[80] The effect of these provisions was succinctly analyzed by Addy J. in *Teledyne Industries Inc. v. Lido Industrial Products Ltd.*[29] at p. 227. He observed that s. 3 constitutes the Federal Court of Canada a court of law, equity and admiralty and that s. 20 also specifically grants it jurisdiction in equity respecting patents of invention, copyright, trade mark and industrial design. Thus, even though it is a statutory court rather than one of general jurisdiction, when the subject-matter is otherwise within the Federal Court's jurisdiction and where equitable principles are applicable to the issue, the Federal Court may exercise all the powers and enforce all the remedies available to a court of equity dealing with that same issue. It can do so because it is a court of equity. Justice Addy noted that the right of its predecessor, the Exchequer Court of Canada, to apply equitable principles and to enforce equitable remedies had always been recognized.

[81] In *Algonquin Mercantile Corp. v. Dart Industries Canada Ltd.*,[30] Justice Addy addressed the point again and put it this way:

> Once it has jurisdiction and subject only to any specific statutory provision to the contrary, the Federal Court of Canada may, in determining the issues before it, exercise all of the powers and enforce all of the remedies available to both courts of law and courts of equity. In other words, to dispose of any case before it, it may exercise the same

---

[29] (1982), 68 C.P.R. (2d) 204 (F.C.T.D.).
[30] (1986), 12 C.P.R. (3d) 289 (F.C.T.D.).

> powers and apply the same laws and principles as the Superior Court of the province where the cause of action lies. [31]

[82] One final reference will assist in understanding the concurrent jurisdiction of the Federal Court relative to the Superior Courts of the provinces. That is the decision of the Supreme Court of Canada in *Canada (Human Rights Commission) v. Canadian Liberty Net*[32], a case that dealt with the Federal Court's jurisdiction. The issue was the power and jurisdiction of the Federal Court to enjoin hate type messages. The argument made there, in part, was that wherever a "gap" is perceived in the jurisdiction of the Federal Court, only the Superior Courts of the provinces can grant relief. Bastarache J. writing for the majority, said at paras. 33-38 that that was not the case. Even in circumstances where there might be considered to be a gap in the Federal Court's jurisdiction, it will in fact have jurisdiction where it necessarily relates to matters that do fall within its jurisdiction.

[83] This jurisprudence leaves the unavoidable and necessary implication that the Federal Court has all the powers of the Superior Court when dealing with a subject-matter that is within its jurisdiction, thus according it all of the powers to grant or enforce all of the remedies available to the Superior Court, so long as there are no specific statutory provisions to the contrary. It necessarily follows that equitable jurisdiction in the Superior Court is not wider than that of the Federal Court when dealing with a subject-matter within the jurisdiction of the Federal Court.

Is this an appropriate case for summary judgment?

[84] Rule 20(4), as it was amended, requires that summary judgment be granted where there is "no genuine issue that requires a trial." Controlling appellate guidance provided in *Combined Air*[33] and the other cases decided at that time emphasizes that the principal factor in determining whether summary judgment should be granted will be whether a fair and just determination of the claim can be achieved through the summary judgment process. If it cannot, the matter must proceed to trial because the purpose of the rule is not to eliminate all trials, just to eliminate unnecessary trials.

[85] The first question is whether the motions judge can have the "full appreciation" of the evidence and the issues necessary before dispositive findings can be made. It is only appropriate to determine a matter by summary judgment where that "full appreciation" can be achieved – not just a full appreciation of the motions materials,[34] but a full appreciation of the case in its entirety. Only after this question has been affirmatively answered may a motions judge carry on and consider whether there is a genuine issue that requires a trial. Once a court concludes that it can achieve a full appreciation of the evidence without the need for a trial, it may then take account of the developed case law that remains applicable relative to summary judgment motions and the evidentiary and persuasive burdens that those authorities impose on the parties.

---

[31] The decisions were affirmed by the Federal Court of Appeal in *Voith (J.M.) GmbH v. Beloit Group* (1997), 214 N.R. 85 (F.C.A.), at paras. 109-114.
[32] [1998] 1 S.C.R. 626.
[33] 2011 ONCA 764, 108 O.R. (3d) 1.[34] Ibid., at para. 53.
[34] Ibid., at para. 53.

[86] In this case, the parties do not agree that the matter can or should be dealt with by way of a summary judgment motion. Apotex opposes the use of the summary judgment procedure in this case for several reasons.

[87] First, it claims that the principles of law that underlie Abbott and Takeda's claim for summary judgment are unsettled and that the court should not decide a significant question of law in those circumstances. Apotex claims that this is a complex issue that needs to go to trial. Curiously, counsel for Apotex acknowledged that there is a factual disagreement, yet suggested there would be "further evidence to be presented at trial" which was not present on this summary judgment motion. Counsel suggested that this further evidence would relate to the question whether s. 8 of the *NOC Regulations* displaces or ousts Apotex's claim to disgorgement of the defendants' revenues or profits on the basis of equitable principles of unjust enrichment.

[88] Secondly, Apotex claims that the record before this court is not complete, even though it acknowledged in argument that the validity of the September 2008 settlement agreement is not in dispute between the parties. I also found the assertion that the record is somehow incomplete to be curious given Apotex's failure to examine or cross-examine *any* parties in accordance with the case managed schedule that I set for these parties leading to this special summary judgment hearing appointment, and even though Apotex acknowledged in argument that "there is no need here for more evidence relative to the issues in dispute between these parties."

[89] Nevertheless, Apotex insists that the record here is not enough, that more is needed, and that accordingly, summary judgment is not appropriate. It suggests that when I ask myself "[W]hat more do I need to decide this question?", that I ought to conclude that I do not have enough. That is because, it says, the case here is about whether the court is able to extend the statutory damages time referred to in s. 8 of the *NOC Regulations*. Absent an answer to that question, Apotex claims I cannot have a full appreciation of the matter because that leaves an unsolvable gap. It proffers a number of decisions that it claims support its position that this is not a suitable case for a summary judgment motion, including *Romano v. D'Onofrio*,[35] *Baglow v. Smith*,[36] and *Allen v. Succession Capital Corp.*[37]

[90] Respectfully, I disagree. First, relative to the scope of the s. 8 damage remedy and having regard to the comprehensive Federal Court of Appeal decision in *Apotex v. Eli Lilly*, whether the court or the parties have the right to extend the s. 8 statutory damages period does not in any way, in my view, undermine the defendant's claim on this summary judgment motion. That claim of the defendants here is that: (i) s. 8 constitutes a "complete code" relative to the quantum of damages that may be obtained; and, (ii) the ability to claim equitable remedies or a greater amount of relief via disgorgement using equitable principles is ousted. It is a position that relates to the standard against which the quantum of loss of the generic manufacturer is to be measured and for which compensation may be obtained, not the duration of the period for which such compensation may be obtained.

---

[35] (2005), 77 O.R. (3d) 583 (C.A.), at para. 7, citing *Bendix Foreign Exchange Corp. v. Integrated Payment Systems Canada Inc.*, [2005] O.J. No. 2241 (C.A.).
[36] 2012 ONCA 407, 110 O.R. (3d) 481.
[37] 2011 ONSC 3300.

[91] More importantly, returning to the fundamental principles in *Combined Air*, I agree with counsel for Abbott and Takeda that the documentary record is sufficient for me to have a "full appreciation" of the evidence and the issues that are required in order to make dispositive findings based on this record. This is not a case that involves or will necessitate multiple findings of fact on the basis of conflicting evidence emanating from a number and variety of witnesses and found in a voluminous record. In circumstances where the evidentiary sources involve a broad number of witnesses, a summary judgment motion could not serve as a substitute adequate to replace the trial process. In cases like that, the interests of justice require a trial because dispositive findings of fact can only be made in the cauldron of a trial that permits the trial judge to assess the evidence of witnesses and the extent to which that evidence stands up under cross-examination.

[92] Rather, this is a case that is largely driven by documents and a statutory and regulatory framework, with virtually no testimonial evidence. This is not to say that there are no disagreements between the parties in this case, but as in *Canadian Soccer Assn. v. Hyundai Auto Canada Corp.*,[38] simple allegations of a breach of contractual terms or disagreement on the meaning of language used by parties in reaching an agreement does not necessarily mean that a trial is required in order to determine the matter. The question to be asked is whether there is sufficient evidence to allow a judge to fairly decide the issues that are raised on the summary judgment motion. In that case Smith J. concluded at paragraph 29 that:

> Given the positions of both parties that there were no issues of material fact, credibility inferences or weighing of evidence required at trial, and based on the largely uncontested evidence before me, I find that the moving party has met its onus of showing that there is sufficient evidence before the Court to make findings of fact necessary to decide the issues on their merits on a motion for summary judgment.

[93] In my view, this case is no different. Here, extensive directions were provided to counsel in the course of the case management process that led to this hearing. Counsel agreed with those directions. The framework provided more than adequate time to permit both parties to conduct examinations for discovery, to adduce additional substantial evidence, to conduct cross-examinations if they required them, and to prepare *facta* and books of authorities. The minutes of the case management conference attended by counsel for all parties by conference call on July 10, 2012, three and a half months before the motion was heard, set out the agreed timelines on all of these points. All counsel assured me in the course of that case management conference that this timeline was adequate to permit required examinations to take place. No complaint was ever made that it was not.

[94] As it turned out, Apotex (and all parties for that matter) declined to conduct *any* examinations for discovery. They waived discovery. Apotex did not adduce *any* substantial evidence or conduct *any* cross-examinations. As such, given the opportunity it had to adduce evidence that it thought relevant or appropriate or necessary on this summary judgment motion, it does not lie in the mouth of Apotex to now claim that further evidence will be adduced at trial.

---

[38] 2011 ONSC 801.

[95] Under the old summary judgment rules, the case law clearly established that all parties had to put their best evidentiary foot forward. In particular, it was inadequate for a responding party on a motion for summary judgment to claim that further and better evidence to resist the moving parties claim would materialize prior to trial. That is entirely different from circumstances where the *viva voce* testimony of witnesses and their cross-examination must be heard in the context of a trial to permit an appropriate disposition of the matter. To accept such a claim would prevent the achievement of the very goal that the amended summary judgment motion rules were designed to meet.

[96] Further, Apotex takes the position that the question of law that is central to this motion is undecided and cannot be determined on this summary judgment motion. However, I find the case law advanced by Apotex in support of that position to be entirely distinguishable. Apotex asserts, erroneously in my view, that summary judgment is not and cannot be appropriate where the law is unsettled. The case law it put forward is alleged to support that proposition, but each of the three cases advanced were cases involving significant components of factual discord or uncertainty that precluded the court from having the full appreciation that *Combined Air* requires before summary judgment may be granted. Further, the quotations set out in Apotex's factum are incomplete. Contrary to the proposition that Apotex claims those cases stand for, each of those cases actually confirms that a motions judge *can* decide questions of law that are unsettled, *provided* that a complete factual record is present. In this case, not only is it incorrect to suggest that the factual record present here is incomplete, but more importantly, as the analysis below will show, the question of law in issue is no longer unsettled.

[97] The *Baglow* decision relied on by Apotex postdates *Combined Air*. As Justice Blair observed, that appeal arose out of the "fervent, if not florid" expression of views of "commentators engaging in the cut and thrust of political discourse in the Internet blogosphere." The issue was whether an exchange of statements published on an Internet blog ought to have different legal considerations apply in determining whether or not they are defamatory as compared to statements made in the context of the Internet media, including publications on social media sites such as Facebook or in the "Twitterverse."

[98] It was not surprising to me in that case that the Court of Appeal concluded that the case was not appropriate for summary judgment. The reasons were twofold. First, it indicated in paragraph 29 of its reasons that those issues had not been addressed in the jurisprudence in any significant way, but acknowledged that the answer might have far reaching implications and would thus best be crafted on the basis of a full record after a trial, "at least until the law evolves and crystalizes to a certain point." Second, it noted that a summary judgment proceeding was inappropriate, not because the parties had failed to *exercise* their rights of cross-examination, as the motions judge incorrectly stated, but rather because the procedure itself, by definition, entails no rights of cross-examination. Under Rule 76, cross-examination of the deponent on an affidavit is not permitted. In summary, this caused Blair J.A. to conclude at paragraph 35 that:

> While the motion judge did have an extensive record before him in the form of the entirety of the exchanges between the parties, this was not sufficient in my opinion. It cannot be said that this is simply a "document-driven case," or that this is a case involving "limited contested evidence," as contemplated in the passage above, such that

> "both the full appreciation test and the efficiency rationale may be served by granting summary judgment in the simplified procedure action."

[99] Similarly, in *Allen v. Succession Capital Corp.*, where the core issues related to intentions of the parties and turned on a credibility contest between the parties, Goodman J. concluded that the true intentions of the parties was best left for resolution at trial, rather than on a summary judgment motion "based on the incomplete record before me which is replete with competing affidavits and various interpretations."

[100] In contrast, here there is no need for further testimony of witnesses to inform the background against which these issues ought to be decided. Moreover, Apotex's opportunity to advance "further possible facts" is now gone. There are no competing affidavits present in this case, and having had the opportunity to put forward evidence, Apotex chose not to do so. In my view, there is no incomplete record.

[101] Moreover, the findings I am called upon to make are principally document driven, based on the record that has been put before the court. Of equal importance, the key issue to be determined on this motion is a question of law.[39]

[102] It is particularly appropriate for that question of law to be determined in this case, given that the recent appellate judicial developments referenced above now cause it to be a settled question in my view. Even if that were not the case, however, and even if the question is considered to still be unsettled, it is appropriate for this court to determine such an unsettled question of law on the motion if it is in as good a position as the trial judge would be to determine that issue.[40]

[103] In this case, I find that it is possible have a "full appreciation" of the evidence and the issues necessary to permit dispositive findings to be made because on this summary judgment the court does have the benefit of a full evidentiary record. I find that this is a case where it is both possible and appropriate to determine the matter by summary judgment.

Should this court follow the decision in *Apotex v. Eli Lilly Canada Inc.*?

[104] Abbott and Takeda seek partial summary judgment dismissing Apotex's claim for disgorgement of their revenues or profits. That claim is based on a simple legal proposition – that Apotex cannot obtain that unjust enrichment-based remedy against them in this court because the decision of the Federal Court of Appeal in *Apotex v. Eli Lilly Canada Inc.*[41] has resolved the issue against Apotex. In their submission, the authority of that decision establishes that Apotex's damage entitlement in this case for their alleged but unspecified violation of the *NOC Regulations* is now limited to the remedy provided under s. 8 of those regulations.

---

[39] *Combined Air; Moorefield Excavating Ltd. v. Arran-Elderslie (Municipality)*, 2012 ONSC 1744, 214 A.C.W.S. (3d) 127, at para. 3.
[40] *Aronowicz v. Emtwo Properties Inc*, 2010 ONCA 96, 98 O.R. (3d) 641, at para. 71.
[41] 2011 FCA 358.

(i) What did the Federal Court of Appeal decide?

[105] Abbott and Takeda argue that this is the key decision on this motion for summary judgment because: (i) it definitively establishes the s. 8 remedies under the *NOC Regulations* as a complete code; and, (ii) it definitively rejects the availability of disgorgement of an innovator's revenues based on unjust enrichment, absent extraordinary egregious circumstances. In the absence of those facts, they claim partial summary judgment against Apotex in this case.

[106] The court's reasons in *Apotex v. Eli Lilly Canada Inc.* were written by Noel J.A., who also wrote the reasons in *Merck*. In *Eli Lilly*, Apotex recognized that s. 8 of the *NOC Regulations* did not entitle it to any quantum of damages but contended that unjust enrichment was a *different* cause of action, independent of s. 8, and that the disgorgement remedy flowed from that independent cause of action. Apotex acknowledges that the decision in *Merck* determined that the scope of damages available to generics under s. 8 was limited, but it argues that decision was silent on whether disgorgement of profits could be obtained by an independent action.

[107] The nub of Apotex's claim in *Eli Lilly* was that the innovators would improperly realize a financial windfall to which they were not entitled solely because of its absence from the marketplace as a low cost competitor. This theory was grounded in its complaint that it was only excluded from that market because of the innovators' "wrongful invocation" of the *NOC Regulations*. However, the only "material" fact that Apotex advanced to support its characterization of the innovator's conduct as "wrongful" was that the NOC prohibition proceedings initiated by the innovators were dismissed.

[108] Clearly, the regulatory stay that arose in favour of the innovators on the commencement of the NOC prohibition proceedings delayed the issuance of a NOC to Apotex. However, it is that exact circumstance that s. 8 contemplates as the potential source of a generic manufacturer's entitlement to a damages remedy – indeed, Apotex made the exact same allegation in support of its s. 8 damages claim.

[109] It was significant to Noel J.A. in *Eli Lilly* that the innovators were not alleged to have committed any other "wrongful" act. He compared this, for example, to *Apotex Inc. v. Laboratoires Fournier S.A.*,[42] where abuse of process by the innovator was also alleged. However, given that the extent of the alleged wrongful conduct was the innovators simply availing themselves of the very procedures that were contemplated in s. 8 and the other provisions of the *NOC Regulations*, unsuccessfully as it turned out, the question there was whether Apotex could have any hope of successfully invoking s. 20(2) of the *Federal Courts Act* to obtain the additional remedy which it sought.

[110] The answer to that question was no. In the court's view, Parliament had considered the question of whether a remedy should be available to generics in such circumstances and the extent of that remedy. It did so through the delegated authority of the Governor-in-Council in a purposeful attempt to strike a balance between the need for patent protection on the one hand,

---

[42] [2006] O.J. No. 4555, 54 C.P.R. (4th) 241 (H.C.J.), at para. 25. In that case, Apotex pleaded the constituent elements of the tort of abuse of process, as established in *R. Cholkan & Co. v. Brinker* (1990), 71 O.R. (2d) 381 (H.C.J.), as well as conspiracy to commit that tort.

and the timely entry of lower priced drugs on the market on the other. In the court's view, s. 8 fit squarely within that compromise.

[111] Further, the court acknowledged that no one was happy with the result, as tends to be the case with compromise solutions. The innovators did not believe that they should be required to pay damages for using the very procedure Parliament adopted to ensure their patent protection and generic companies argued, as Apotex does again here, that the balance struck did not provide a sufficient disincentive to innovators once account was taken of the negative impact which the "automatic stay" has on the public's access to cheaper drugs.

[112] Regardless of that mutual dissatisfaction, Parliament then chose to take further action to clarify the point and end *any* ambiguity that might have remained after the decision in *Merck*, above. It did so by amending s. 8 in 2006 to remove any reference therein to "profits". At paras. 21-22 of his reasons in *Eli Lilly*, Noel J.A. emphasized the necessary and inevitable certainty of this conclusion:

> Any doubt in this regard was removed by the 2006 amendment which deleted the reference to the word "profits" in s. 8. The Regulatory Impact Analysis Statement (RIAS) which accompanied this amendment explained the change as follows:
>
> > The Government is aware of a number of ongoing s. 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the *PM(NOC) Regulations* by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits ...
>
> After referring to the introduction of related measures, the RIAS concluded:
>
> > ... The Government believes that this line of argument should no longer be open to generic companies that invoke s. 8. [Noel J.A's emphasis.]
>
> When regard is had to this amendment, and the decision of this Court in *Merck F.C.A.*, the matter could not be any clearer. Parliament, through the auspices of the Governor-in-Council, has considered whether generic companies should be entitled to the disgorgement of first persons' profits in the circumstances contemplated by s. 8, *and has excluded this remedy*. It did so in the context of the above-noted balance which is sought to be achieved by the *PM (NOC) Regulations. This is a legislative policy issue with respect to which the will of Parliament is paramount.* [Emphasis added.]

[113] For the Federal Court of Appeal, it plainly followed that whatever jurisdiction the Federal Court has to provide equitable relief under ss. 20(2) of the *Federal Courts Act*, it cannot be used to grant a remedy which s. 8 was intended to exclude, absent a cause of action being alleged that

is independent of the operation of s. 8. Since no such cause of action had been pleaded by Apotex in that case, just as no such cause of action independent of s. 8 has been pleaded by Apotex in this case, its unjust enrichment-based claim for disgorgement of profits could not possibly succeed there, and in my view, it cannot possibly succeed here.

[114] Notably, the Federal Court of Appeal also commented at para. 24, on the decisions of Whitaker and Swinton JJ., in the earlier motions to strike Apotex's pleadings in this action and the leave to appeal application that followed, both of which were drawn to its attention. Given the complete nature of the regulatory regime, the court found it difficult to comprehend how an unjust enrichment-based disgorgement of profits remedy could be found in the context of s. 8 damages in the absence of egregious facts being attributed to an innovator company beyond merely initiating prohibition applications as contemplated by s. 8.

(ii) Why should that decision be followed?

[115] In my view, there are five reasons why this court must follow the reasoning of the Federal Court of Appeal in *Apotex v. Eli Lilly* and grant the partial summary judgment sought by Abbott and Takeda in this particular case.

Reason One

[116] First, stated simply, the decision of the Federal Court of Appeal ought to be followed because it plainly and conclusively determines that unjust enrichment is not an available remedy to Apotex in the circumstances of this case.

[117] *Eli Lilly* is obviously a considered decision of an appellate court that has vast experience in the interpretation of the *NOC Regulations*. Further, the strong and pointed reasons for judgment in the case were written by one of the most senior and experienced jurists on that court, Justice Noel, the same judge who wrote the unanimous reasons for the Federal Court of Appeal on the earlier *Merck* decision. Justice Noel wrote that decision at a point in time when Parliament had not yet amended s. 8 of the *NOC Regulations* to clarify its intent. When it did, it clearly stated that the damages framework in s. 8 was meant to be exclusive and all-embracing, absent the presence of elements that would found a separate and distinct cause of action, such as under the heading of abuse of the procedure provided for under the *NOC Regulations*.

Reason Two

[118] The second aspect to the Federal Court of Appeal's decision in *Eli Lilly* that commends itself in this case is the very absence of factual elements which would permit Apotex to access the remedy it seeks. Contrary to the suggestion made by Apotex in its argument, it is plain to me that the Federal Court of Appeal does contemplate that there is still possibly room for an equitable remedy to give rise to damages payable by an innovator in favour of a generic manufacturer, albeit in very limited circumstances. Those limited circumstances can arise where there is a cogent factual foundation that could support a plea of abuse of procedure against an innovator manufacturer, as was considered possible in the *Apotex v. Laboratories Fournier S.A.* decision. Justice Noel specifically acknowledges that point at paragraph 16 of his reasons in *Eli Lilly*.

[119] *Apotex v. Laboratories Fournier S.A.* was a 2006 decision, again on a motion to strike a pleading in this court brought under Rule 21. Given his conclusion that the state of law *at that time* was embryonic relative to the scope of the s. 8 damage remedy under the *NOC Regulations*, and given the court's reasoning in an earlier *Eli Lilly* decision,[43] Belobaba J. could not fairly conclude at that time, before this Court of Appeal decision was rendered, that Apotex's claim regarding s. 8 damages against the defendants in that case had no chance of success and was certain to fail.

[120] More importantly, however, Belobaba J. noted that tort liability was also present in the allegations of conspiracy and that it was inappropriate to strike that pleading to the extent that the defendant in that case was potentially caught as a joint tortfeasor in the actionable wrong of abuse of process. That tort, allegedly consisting in that case of the "improper institution and continuation" of prohibition proceedings in the Federal Court, requires two constituent elements: (1) a collateral and improper purpose in bringing legal proceedings; and, (2) a definitive act or threat in furtherance of that collateral purpose.[44]

[121] No guidance was provided there, however, on what facts might be required to establish an improper initiation and continuance of prohibition proceedings. Whatever those circumstances might be, they are not circumstances that can be applicable in this case, as neither of the required elements is pleaded. In this case, the statement of claim is in *all* material respects the same, that is, effectively *identical* to the statement of claim that underlay Apotex's claim of an unjust enrichment-based remedy in the 2011 *Eli Lilly* case.

[122] In both cases, the innovators are accused of wrongly invoking the *NOC Regulations*. In both cases, it is claimed that wrongful invocation of those regulations will generate a windfall for the innovator, even if it is compelled to compensate Apotex under s. 8 of the *NOC Regulations* for damages flowing from its exclusion from the marketplace. In both cases, Apotex claims the innovator has no entitlement and that there is no juristic reason for the innovator to retain any windfall attributable to sales while Apotex was off the market. Most importantly, in both cases with the exception of a change of one word, Apotex claims as follows:

> In the absence of a disgorgement of this unjust enrichment, every patentee would have an incentive to use the *Patent Regulations* in all cases to unjustly delay entry of every generic product at the expense of the generic manufacturer, in the knowledge that the revenues made by it would exceed the damages for which it will be liable for the delay caused to the generic manufacturer.[45]

[123] Regardless of its protestations, I can find *no* evidence here of any wrongful invocation of the *NOC Regulations* by Abbott or Takeda. No evidence is advanced by Apotex to demonstrate

---

[43] *Apotex Inc. v. Eli Lilly and Co.*, [2005] 2 F.C.R. 290 (F.C.A.).

[44] See: *R. Cholkan & Co. v. Brinker.*

[45] Compare paragraphs 20, 22 and particularly 23 of the statement of claim in this action, CV-09-391938 to paragraphs 22, 23, 24 and particularly 25 of the statement of claim and *Apotex v. Eli Lilly*, action A-173-11. The difference in wording between paragraph 23 of the statement of claim and paragraph 25 of the statement of claim in the Federal Court action is the reference to "generic manufacturer" on two occasions, rather than referring to the "Generic".

any fault on the part of Abbott or Takeda in pursuing prohibition remedies to which they were entitled under the specific terms of the *NOC Regulations*. Apotex chose not to advance *any* evidence on this summary judgment motion beyond what was in the record before the court, notwithstanding the opportunities it, and all parties, were given. Indeed, as argued by counsel for Abbott and Takeda, it seems plain that this is a case where the evidence is even stronger *against* any notion of a wrongful invocation of the *NOC Regulations* than was the situation in *Eli Lilly*.

[124] I can see no basis upon which Apotex could allege wrongful invocation of those regulations here because this litigation was actually settled when: (1) still before the Federal Court, at a point in time when Justice Phelan had his decision under reserve; (2) Abbott had already won its case against Novopharm; and, (3) it is plain that the dismissal of the prohibition proceedings brought by Abbott and Takeda against Apotex was on *consent* and was specifically agreed to by Apotex. It is disingenuous in these circumstances to make any accusation of any wrongful conduct.

[125] Moreover, it is plain and at the core of the s. 8 damages regime that in some cases innovators will succeed in their prohibition proceedings relative to the generic, while in others they will not. That is exactly what triggers the s. 8 damages entitlement. Parliament was aware of this. It knew some innovators would succeed and some would not, but there is no indication or suggestion in the language of the legislation or the RIAS or in any of the related jurisprudence to suggest that an innovator's failure to succeed on such a case must necessarily amount to the wrongful invocation of the provisions.

[126] If there were facts to the contrary that could pass evidentiary muster for an allegation that the innovators did anything other than simply avail themselves of the procedures contained in the *NOC Regulations* as Parliament drafted and amended them, then perhaps an argument might be made that an unjust enrichment-based disgorgement of profits remedy could arise in particular and limited circumstances that would presumably be rare. However, these are not those circumstances, and to quote Justice Whitaker and his reasons on the motion to strike Apotex's pleadings in this case, "this is not that day."

[127] Noel J.A. specifically concluded that no disgorgement of profits remedy could be available under s. 8 of the *NOC Regulations* having regard to the all-embracing "complete-code" scope of the regulatory framework and the specific amendments made by Parliament to clarify that it was not intended to remain open to generic manufacturers to pursue such a remedy in the context of s. 8 damages. Snider J. emphasized the same point very recently in *Sanofi-Aventis Canada Inc. v. Teva Canada Ltd.*[46] when she observed that damages that are available to a generic manufacturer in these circumstances are entirely statutory because they only arise out of the operation of the statutory regime, and that it is settled law that there are no remedies beyond that framework.

[128] I can see no relevant factual basis here to distinguish this case from the circumstances that were before the Federal Court of Appeal in *Eli Lilly*. Moreover, as noted, there is nothing in the settlement agreement that permits, contemplates or suggests that Apotex can commence an action for unjust enrichment. I agree with counsel for the moving parties that Apotex conceded in

---

[46] 2012 FC 552, at para. 14.

paragraph 80 of its factum that the settlement agreement only dealt with the s. 8 damages entitlement and nothing else.

Reason Three

[129] The third reason why this court should follow the Federal Court of Appeal's decision is that Apotex sought leave to appeal that decision to the Supreme Court of Canada, but leave to appeal was denied. On May 17, 2012 a three judge panel consisting of McLachlin C.J.C., and Rothstein (formerly of both the Federal Court and the Federal Court of Appeal, who wrote for the Supreme Court of Canada in the decision in *Merck*) and Moldaver JJ., denied leave.[47]

[130] While decisions of the Federal Court of Appeal are entitled to great deference by this or any other court, just as a decision of any appellate court is entitled to deference and respect, I do acknowledge that it is not a decision that is binding on me, even if it is clearly persuasive and of high authority. Indeed, relative to its persuasive qualities and entitlement to respect, I would note that Federal Court of Appeal decisions have previously been specifically adopted into Ontario law. In *Kanda Tsushin Kogyo Co. v. Coveley*[48] for example, a well-known injunction related decision of this court, Farley J. noted the Divisional Court's concurrence and adoption of the Federal Court of Appeal's view in *Syntex Inc. v. Novapharm Ltd.*[49] and *Centre Ice Ltd v. National Hockey League*,[50] that evidence of irreparable harm in an injunction case must be clear and not speculative.

[131] While it might be tempting in these circumstances to regard the Supreme Court's refusal of leave to appeal as tantamount to its adoption of the reasoning of the Federal Court of Appeal and the equivalent of that decision having been upheld, that would somewhat overstate the proposition. Nevertheless, in a number of decisions judges have interpreted a matter as settled when the Supreme Court of Canada has denied leave to appeal.

[132] Subsection 40(1) of the *Supreme Court Act*,[51] governs leave to appeal to that court. Stated simply, it stipulates that an appeal will lie in a proper case, where the Supreme Court is of the opinion that it ought to decide any question involved in the particular case, given its nature or significance, its public importance, or the importance of any issue of law or any issue of mixed law and fact involved in that question.

[133] In at least two civil cases, one actually a previous Apotex case, judges have ascribed significance to the Supreme Court's denial of leave to appeal.[52] In *Apotex Inc. v. Merck & Co.*,[53] Malone J.A. stated at para. 43 that:

---

[47] *Apotex Inc. v. Eli Lilly Canada Inc.*, [2012] S.C.C.A. No. 78.
[48] [1997] O.J. No. 56, 96 O.A.C. 324 (Div. Ct.).
[49] (1991), 36 C.P.R. (3d) 129 (F.C.A.), at p. 135, leave to appeal to S.C.C. refused 39 C.P.R. (3d) v, 137 N.R. 39.
[50] [1994] F.C.J. No. 68, 53 C.P.R. (3d) 34 (F.C.A.), at p. 54; see also *Willow Corp. v. McDonald's Restaurants of Canada Ltd.*, [1994] O.J. No. 1169, at para 7; *Risi Stone Ltd. v. Omni Stone Corp.*, [1989] O.J. No. 103.
[51] R.S.C., 1985, c. S-26.
[52] See also, in a criminal law context: *R. v. Mallery*, 2008 NBCA 18; *R. v. Investors Group Trust Co.*, 2007 SKCA 132; *R. v. Miron*, [2000] M.J. No. 500 (Prov. Ct.), at para. 38; and *R. v. Ramji*, [1989] 103 A.R. 23 (Prov. Ct.), at para. 5, where Cioni Prov. Ct. J. found an Ontario Court of Appeal decision to be highly persuasive as high authority and "strengthened by leave to appeal being denied by the Supreme Court of Canada."

> In my analysis, there is no question that issue estoppel should *prima facie* apply with respect to Apotex's section 12 argument in this case. The parties are identical, and the issue has been conclusively decided in a judgment of this Court *which must be deemed to be final, given that leave to appeal to the Supreme Court was denied.* [Emphasis added.]

[134] Similarly, in *Hongkong Bank of Canada v. Phillips*,[54] Clearwater J. made the same point at para. 26 when he observed that the Ontario Court of Appeal decision in *Standard Investments Ltd. v. Canadian Imperial Bank of Commerce*[55] relative to fiduciary obligations and unconscionable transactions had effectively been upheld when leave to appeal to the Supreme Court of Canada was denied.

[135] There may be many reasons why the Supreme Court chooses not to grant leave to appeal in particular circumstances and particular cases. Nevertheless, it seems intuitive to me that even if refusal of leave does not amount to an imprimatur, it must be regarded as the acceptance by the Supreme Court of a strong decision by the Federal Court of Appeal for what it is and for what it says, and a determination faced with that decision that leave need not or ought not to be granted. This clearly supports added weight being ascribed to the correctness of the decision.

Reason Four

[136] The fourth line of reasoning why I find that this court must follow the Federal Court of Appeal's decision relates specifically to the reasons that are advanced by Apotex why I should not follow it.

[137] At paragraph 27, 28 and 29 of its factum, Apotex says that while Abbott and Takeda claim that the law is now crystal clear, they fail to address the subsequent decision of Justice Macdonald in *Apotex Inc. v. Eli Lilly and Company*, that it is not plain and obvious that the *NOC Regulations*, and in particular s. 8, limit the common law or equitable claims the plaintiff may make in reliance upon them. In that case, J. Macdonald J. allowed an unjust enrichment plea to continue.

[138] Further, Apotex asserts that "all of the decisions in Ontario, both before and after the Federal Court of Appeal decision in *Apotex Inc. v. Eli Lilly*, have permitted a claim in unjust enrichment to proceed." Moreover, it is claimed that Swinton J.'s decision on the leave to appeal application does bind me under the doctrine of *stare decisis* on the basis that she was sitting in an appellate capacity as a motions judge in Divisional Court, and that I am bound "to follow decisions of courts of co-ordinate authority in the absence of strong reasons to the contrary", citing *Asper v. Lantos*[56] and *Lilydale Cooperative Ltd. v. Meyn Canada Inc.*[57]

[139] While those decisions may have "permitted" Apotex's unjust enrichment claims to escape having their pleadings struck, it is a far cry from suggesting, as Apotex seems to do

---

[53] 2002 FCA 210, [2003] 1 F.C. 242.
[54] [1997] M.J. No. 134 (Q.B.).
[55] (1986), 22 D.L.R. (4th) 410.
[56] (1999), 46 O.R. (3d) 238 (S.C.J.), at para. 7.
[57] (2007), 84 O.R. (3d) 621 (S.C.J.), at para. 36.

inferentially, that its position has received *any* substantive approbation or judicial support on the merits. This overstatement fails to recognize that the decisions referred to by Apotex involve motions to strike pleadings that embrace different tests and sets of assumptions then those that are to apply in a context like this, where the moving parties seek summary judgment dismissing Apotex's claim on the basis that there is no genuine issue for trial. To treat them as the same, or to suggest that any substantive finding that binds me has been made on the merits of Apotex's position in any of the Ontario decisions to date, other than on an assumed set of facts, is overreaching. In my view, the prior decisions of this court are distinguishable and do not require that I follow them.

[140] Looking first at the previous decisions of Justices Whitaker and Swinton in this particular case, it is plain that both decisions were rendered *before* the Federal Court of Appeal issued its reasons in the *Eli Lilly* appeal *on the merits*. As such, when those decisions were written, there was no appellate guidance that had been provided at the Federal Court of Appeal or any other appeal court in Canada relative to the availability as a substantive matter of an unjust enrichment remedy in the context of s. 8 of the *NOC Regulations* as it read *after* being amended by Parliament in 2006.

[141] Unlike before this court, Justice Whitaker evidently heard no detailed analysis in support of the "complete code" theory relative to s. 8 of the *NOC Regulations*. As mentioned above, he concluded that that proposition was not "plain and obvious" but rather somewhat "muddy". Even so, he did allow that the "complete code" theory advanced by Abbott might someday be found to be correct, but as he observed, that is not the test on a motion to strike.

[142] However, even if it may have been muddy at that time, the Federal Court of Appeal judges obviously considered it to have been clarified considerably by the time they delivered their decision in the *Eli Lilly* appeal. There is nothing "muddy" in the crystal clarity of Justice Noel's language, especially once regard is had to Parliament's 2006 amendment of the *NOC Regulations* and to the court's own earlier decision in *Merck F.C.A.*. It seems to me that the matter could not be any clearer.

[143] The same is true to the very thorough reasons of Justice Swinton on the leave to appeal application arising out of Whitaker J.'s decision, also heard and decided before the Federal Court of Appeal's decision in *Eli Lilly*. Taking that timing into account, it is not surprising that she reached the conclusion that she did. As she observed in paragraph 10, there were no cases at that time that had been decided on the issue whether the decision of the patentee to commence an ultimately unmeritorious proceeding under the *NOC Regulations* might give rise to a cause of action in unjust enrichment by the generic drug manufacturer. Further, even though she did not need to resolve the question, it appeared to Swinton J. that the law was not settled on the circumstances in which a statute could provide a juristic reason for unjust enrichment, and that it was not settled that the *NOC Regulations* constituted a "complete code."

[144] Nonetheless, Justice Swinton did not and could not have made a determination of the issue that is before this Court on the merits for the simple reason that it was not a question that was before her and over which she had jurisdiction. She simply made a determination of whether leave to appeal ought to be granted from a decision of Justice Whitaker not to strike pleadings. She made that decision on the basis that it was not plain and obvious at that time, assuming all of

the pleadings were true and correct as a motion to strike requires, that an action in unjust enrichment might not succeed.

[145] Again, Justice Swinton did not have the benefit of the Federal Court of Appeal's decision when she was considering her decision. Neither, evidently, did she have the benefit of the RIAS before her, which clarified Parliamentary intent relative to the 2006 amendment to the *NOC Regulations*. Justice Noel addressed that point in his reasons for *Eli Lilly*, noting that Parliament had specifically considered whether generic companies should be entitled to disgorgement of profits "in the circumstances contemplated by section 8", but had excluded that remedy. He chose to characterize that as "a legislative policy issue with respect to which the will of Parliament is paramount." I share that assessment.

[146] Finally under this reason, I turn to the decision of J. Macdonald J. on the second motion to strike pleadings. In his reasons on the *Apotex v. Eli Lilly* motion to strike, Justice MacDonald reviewed the development of the law of unjust enrichment, as seen in *Kerr v. Baranow.*[58] Although it is a family law decision, the court did explore principles governing unjust enrichment. Taking account of the "remedial flexibility" of unjust enrichment "to deal with different circumstances according to principles rooted in fairness and good conscience",[59] J. Macdonald J. concluded that there was room for an accounting of profits and for an order of disgorgement to develop further as a remedy for unjust enrichment. He did qualify that view, however, by acknowledging that it would depend upon the particular facts of the case. Nevertheless, he considered that it would remain "unduly rigid" to deny Apotex the possibility of an accounting of the innovators' profits and disgorgement of those monies based on unjust enrichment.

[147] Apotex relies extensively on J. Macdonald J.'s decision on that second motion to strike pleadings. It advances it as evidence of the thinking of this court and the choice of a direction different from that pursued by the Federal Court, but in my view, that is too broad a characterization of the impact or scope of the decision. Neither, do I consider the decision of Justice J. Macdonald to be binding on me, or to have reached any substantive conclusions of law relative to this motion that would bind this court. First, I would emphasize again that that case was a motion to strike pleadings, which is an entirely different matter from a motion for summary judgment. It was sufficient for him to dispose of the matter to determine, based on acceptance of the allegations set out in the pleadings and assumed to be true, that it was not plain and obvious to him that Apotex's claim could not succeed, or stated otherwise, that it was doomed to failure. This however is a different test than the one I am required to apply on this summary judgment motion.

[148] Further, while Apotex states in its factum that Justice J. Macdonald was "made aware of the Federal Court of Appeal decision" in *Eli Lilly*, I could not discern from his reasons, on their own, that he actually had a copy of that decision. Although *Eli Lilly* was decided and published by that time, and was no doubt of direct relevance to the case at issue, there is no specific reference to the decision in J. Macdonald J.'s reasons, which I found surprising given the typical

---

[58] 2011 SCC 10, [2011] 1 S.C.R. 269.

[59] Per Binnie J. in *Pacific National Investments Ltd. v. Victoria (City)*, 2004 SCC 75, [2004] 3 S.C.R. 575, at para. 13, referenced by Cromwell J. in *Kerr*, at para. 34.

thoroughness of his decisions and since it was the most direct appellate authority on the issue decided to that time. I can only conclude that J. Macdonald J. could not have been made aware of the implications of the *Eli Lilly* decision, before releasing his judgment. I reach that conclusion particularly relative to whether the *NOC Regulations* amounted to a "complete code", since that line of analysis, as discussed below, might on its own have been adequate under the test in *Rawluk* to oust the rights of Apotex and other generic manufacturers to seek a disgorgement of profits remedy in the context of s. 8 proceedings.

[149] Most importantly in the context of a motion to strike pleadings, his conclusion is in the nature of *obiter dicta.*

[150] While J. Macdonald J. considered the issue of ouster of Apotex's rights to claim damages at common law or in equity and the ouster of the rights of other generic manufacturers, he does not appear to have considered the issue of balance contained within the *NOC Regulations* or Parliament's intent that no disgorgement remedy was to be available within the context of s. 8 damages, absent the existence of an independent cause of action outside of the statutory framework. Presumably, this was because this issue was superfluous to the motion to strike that was before him.

[151] In contrast, this case involves a statutory construct. It relates to a framework that was specifically manufactured by Parliament for the purpose of achieving what it regarded as an acceptable policy balance between the protection of the patent rights of innovators and the need of the Canadian public to be able to obtain inexpensive generic pharmaceuticals. This is not a case of ousting pre-existing rights. It is a circumstance where nothing, no rights, existed in a patent context prior to the creation of the statutory framework.

[152] Apotex has argued that the legislation does not oust prior rights and it assumes that there was a pre-existing cause of action, but that cannot be the case in these circumstances. A generic drug manufacturer has no right to patent-related restitution based on unjust enrichment or otherwise that has no statutory background or foundation. Here, the background or foundation and the only source of the entitlement is to be found entirely in the statutory framework that Parliament created, and as is plain from its language, both initially and as amended, and from the Federal Court of Appeal's decision in *Eli Lilly*, that framework constitutes a complete code and does not leave room for any stand-alone equitable remedies.

Reason Five

[153] The fifth line of reasoning why this court ought to follow the Federal Court of Appeal decision relates specifically to the language used by Parliament in enacting and amending s. 8 of the *NOC Regulations*. In my view, the clarity of that language permits one to discern that even if specific and express words were not used to remove a generic manufacturer's cause of action for unjust enrichment, there was a Parliamentary intention to create a complete code which meets the necessary implication test that is the other half of the analysis in *Rawluk v. Rawluk.*[60] Absent cogent evidence of egregious conduct, I find it to be the case that the s. 8 framework is a complete code.

---

[60] [1990] 1 S.C.R. 70.

[154] Certainly, there is a rebuttable presumption at common law that the legislature does not intend to oust common law or equitable remedies, as established in *Rawluk* and relied on by J. Macdonald J. as his authority for concluding that such a right could only be ousted through the presence of plain and explicit statutory language. But no argument appears to have been made before him to address the other half of the equation, that is, that not only express statutory language but *also* necessary implication could serve to rebut the presumption. The point is well accepted in law, and in particular relative to the intendment of statutes.

[155] In *Sullivan on the Construction of Statutes*,[61] at page 441, the learned author notes that:

> The intent is to create an exclusive code may be expressly stated in the legislation or it may be implied from reading the legislation and its relevant context. When an enactment duplicates the common-law, offers a comprehensive regulation of a matter or implements a specific legislative policy choice, the courts are likely to infer that it was meant to be exhaustive. This inference may also be based on implied exclusion, the presumption against a tautology or the unsatisfactory state of the common-law.

[156] She goes on at page 442 to emphasize that resort to the common law is considered inappropriate when the legislation to be applied is broad and detailed enough to offer a comprehensive regulation of the matter in question. That may not constitute the statute as a whole being a comprehensive code, but it may amount to a particular matter in question within the legislation being dealt with by the legislature in such a comprehensive fashion that it is plain that the legislator intended the scheme of that particular matter to be comprehensive and to displace the common law.

[157] That the *NOC Regulations* constitute a comprehensive scheme and a "complete code" for the purposes of this analysis seems well-established. As discussed above, even before the 2006 amendments were introduced to align the *NOC Regulations* with the intention explicitly articulated in the RIAS issued at that time, the case law showed the comprehensive nature of the scheme. This is recognized in at least three decisions of the Federal Court and two earlier decisions of the Federal Court of Appeal.[62] None of those is referenced in the earlier decisions of this court relied on by Apotex that suggest that whether the statutory scheme is comprehensive is uncertain.

[158] Two of these cases can serve as suitable bookends to the legal correctness of the point. Thirteen years ago, the matter was specifically emphasized by the Federal Court of Appeal in *Apotex Inc. v. Canada (Minister of National Health and Welfare)* by Rothstein J.A, when he observed at paras. 27-28 that:

---

[61] Ruth Sullivan, *Sullivan on the Construction of Statutes*, 5th ed. (Markham: Ont.: LexisNexis Canada, 2008).

[62] See: *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (1999), 3 C.P.R (4th) 1 (F.C.A.); *Apotex Inc. v. AstraZeneca Canada Inc.*, 2012 FC 559; *Solvay Pharma Inc. v. Apotex Inc.*, 2008 FC 308, 64 C.P.R. (4th) 246; *Genpharm Inc. v. Canada (Minister of Health)*, 2003 FC 1148, 30 C.P.R. (4th) 67; *Apotex Inc. v. Syntax Pharmaceuticals International Ltd.*, 2005 FCA 424, 47 C.P.R. (4th) 321.

> Paragraph 8(1)(a) specifically provides that a patent holder whose prohibition application is dismissed is liable for the loss suffered by a generic manufacturer for the delay incurred in the issuance of a Notice of Compliance to the generic by reason of the prohibition application. Under subsection 8(4), the Court has been given jurisdiction to make an award of damages or lost profits. Section 8 of the Regulations makes it apparent that the Governor in Council recognized that generic manufacturers could be subject to unjustified prohibition applications, including applications based upon ineligible patents on the Register and provided a remedy in the form of an award of damages or lost profits in such circumstances.
>
> In sum, there is a comprehensive scheme provided in the [Patent] Regulations which specifically addresses ineligible patents on the Register and the costs, loss and damage suffered by generic manufacturers arising from such ineligible patents being included on the Register. Having regard to the scheme and its recognition that ineligible patents may be included on the Register, it follows that there is no unlawful refusal to exercise discretion by the Minister in not deleting such patents from the Register under subsection 3(1).

[159] Then, coming to the present, in his 2012 decision in *Apotex Inc. v. AstraZeneca Canada Inc.*, in a case specifically concerned with the entitlement of this plaintiff, Apotex, to s. 8 damages under the *NOC Regulations*, Justice Hughes had the following to say at paragraphs 99 and 100, tying back to Rothstein J.A.'s conclusion in the 1999 decision:

> It is for Parliament to provide for the appropriate weighing or balancing of interests in enacting the *Patent Act,* and for the Governor-in-Council to do likewise in promulgating the *NOC Regulations*. There is no independent ground for arguing that section 8 of the *NOC Regulations* is invalid, simply because it was not "balanced" in the view of one of the interested parties.
>
> In any event, the Federal Court of Appeal has already held that section 8 is an appropriate part of a "comprehensive scheme" and that the Governor-in-Council recognized the competing interests.

[160] But does this meet the necessary implication test and is it enough to oust the availability of an equitable remedy to Apotex in this case? In my view the answer is that it is and it does.

[161] A legislature is presumed not to depart from prevailing law without displaying its intentions to do so with irresistible clearness.[63] However, irresistible clearness can be achieved through express statutory language *or* by necessary implication through evidence that the

---

[63] *Rawluk v Rawluk*, at para. 36, citing *Goodyear Tire & Rubber Co. of Canada v. T. Eaton Co.*, [1956] S.C.R. 610, at p. 614.

legislature intended its law to constitute a comprehensive regulation over the matter.[64] Decisions of the Supreme Court and this court recognize that the doctrine of necessary implication can serve to rebut the common law presumption enunciated in *Rawluk* that Parliament does not intend to oust common law and equitable remedies absent clear language to the contrary.

[162] In *Reference re: Goods and Services Tax*,[65] the constitutionality of the federal Goods and Services Tax was at issue. It was enacted in 1989 by Part IX of the *Excise Tax Act*, R.S.C., 1985, c. E-15 (*GST Act*). One of the interveners, the Canadian Federation of Independent Business (CFIB), relied upon the common law as the basis for the recovery of expenses it claimed that its members would incur in connection with the collection and remittance of the GST by registered suppliers as an agent of the government.

[163] The CFIB argued that registered suppliers had a common law-based restitutionary entitlement or claim against the federal government for the costs and expenses of collecting the GST based on principles of unjust enrichment and restitutionary recovery. It advanced the Supreme Court of Canada's decision in *Pettkus v. Becker*[66] as authority for that claim. However, the Supreme Court rejected that view.

[164] It concluded that the contended right to compensation was not supported by section 103 of the *Constitution Act, 1867*, by the common law, or by the operation of the *GST Act* itself. If the CFIB members had any right to remuneration for their time and troubles in collecting the tax, it would have to flow from the statute itself. As the Supreme Court said at paragraph 50, "where a statute establishes a scheme providing for compensation, common law rights which might have operated but for the statute cannot be relied upon".

[165] In reaching that conclusion, the court relied on its own decision in *Zaidan Group Ltd. v. London (City)*.[67] It had decided in that case that common law rights which might have operated but for the existence of the statute could not be relied upon in circumstances where a statute establishes a scheme providing for compensation, whether activated or not.

[166] *Zaidan* was a case where a property developer sought to obtain interest on overpayments of municipal taxes that it made under compulsion. It later recovered the overpaid amounts. When it obtained a refund of the overpayments, it also demanded interest on those amounts. The City refused to pay, so Zaidan brought an action to recover the interest. Its claim was upheld by the trial judge, but when the appeal by the City ultimately came to the Ontario Court of Appeal, Zaidan claimed that the City of London would be unjustly enriched if it was not required to pay interest on the overpayments of taxes.

[167] Zaidan might have been surprised that the City's appeal was allowed, and ultimately upheld by the Supreme Court of Canada. The point was that the *Assessment Act*,[68] constituted a complete code for assessing, levying, collecting, and rebating municipal taxes, just as the *NOC*

---

[64] Sullivan, at pp. 441-447; see also *Gendron v. Supply & Services Union of the Public Service Alliance of Canada, Local 50057*, [1990] 1 S.C.R. 1298, at paras. 44-45.
[65] [1992] 2 S.C.R. 445.
[66] [1980] 2 S.C.R. 834.
[67] [1991] S.C.R. 593, aff'g (1990), 71 O.R. (3d) 65 (C.A.).
[68] R.S.O. 1980, c. 31.

Regulations provides a complete code in this case for the damage experienced by generic manufacturers for being delayed in their ability to access the pharmaceuticals market. The *Assessment Act* did not provide for repayment of interest except under a by-law, just as s. 8 of the *NOC Regulations* does not contemplate remedies beyond the parameters established by Parliament. Since the City of London had not passed such a by-law, Zaidan was not entitled to the interest. The legislation was validly enacted so any argument that the City had been unjustly enriched at common law was untenable. It was simply a case, like here, where the common law was superseded by the statutory regime.

[168] Finally, *Gendron v. Supply & Services Union of the Public Service Alliance of Canada*[69] also bears on the point, and is important insofar as it specifically ties in to the analysis in *Rawluk*. In that case, the *Canada Labour Code*,[70] was under consideration. The question as it pertains to this case was whether the ordinary courts had jurisdiction under the *Canada Labour Code* to entertain claims based on a breach of a union's duty of fair representation, and if so, what was the correct test as regards that duty.

[169] The Supreme Court found that the union had a duty to fairly represent the employee. As it relates to this case, the court made a clear and specific finding about common law and statutory remedies. It concluded that unless a statute contains words that expressly "or by necessary implication" oust a common law duty or remedy, one will have a choice of remedies. In that case, however, Parliament had codified the common law duty of fair representation within a larger comprehensive legislative scheme of the *Canada Labour Code* and had provided a new and superior method of remedying a breach. Thus, the common law duty of fair representation was neither necessary nor appropriate in circumstances where the statutory duty applied. Therefore, while the *Canada Labour Code* did not expressly oust the common law duty, it did oust the duty by necessary implication in most situations where the terms of the statute applied. In situations where the statute was silent, did not apply by its terms, or where it might not be clear that the statute exclusively covered the issue, a different result might ensue. Other than in those instances, however, the statutory regime would govern.

[170] In my view, the same ousting of the equitable remedy necessarily arises here after Parliament amended s. 8. In this case, the plain result is that a remedy of unjust enrichment does not exist in the context of the remedies provided in s. 8 of the *NOC Regulations* because Parliament has excluded it.

[171] There was a claim made by Apotex that was clearly an afterthought and add-on that the existence of the contract settling the litigation between these parties might give rise to an extra-statutory remedy at common law or in equity, but I reject that assertion, whatever the intention may have been in raising it. I reject it because Apotex's counsel confirmed before me that there were no issues on this motion that related to the contract, and that the contractual matters were separate and distinct from the existence of the remedy itself. Counsel later tried, unsuccessfully, to retreat from that position during argument. I reject that the contract has any relevance to what is really at stake here, as these reasons should make plain. In any event, I consider the contractual issues to be peripheral to the main issue here, issues that could be resolved by a limited trial of

---

[69] [1990] 1 S.C.R. 1298.
[70] R.S.C. 1970, c. L-1.

issues under Rule 20 if the parties are unable to resolve them having regard to the determination on this summary judgment motion.

(iii) Summary of Findings

[172] The *NOC Regulations* are a delicate and complicated balance of competing interests. Recognition of Apotex's claim to unjust enrichment would frustrate Parliament's policy decision to preclude the disgorgement of the innovator's profits from a claim for s. 8 damages. Section 8 is part of a "complete and comprehensive scheme that both supplies the duty and provides the necessary adjudicative machinery such that resort to the common law is duplicative in any situation where the common law applies."

[173] Just like the Apotex claim that was before the Federal Court of Appeal in *Eli Lilly*, Apotex in this case relies on the *same* delay, caused by the *same* invocation of the *NOC Regulations*, as the basis for *both* its claim under s. 8 *and* its claim in unjust enrichment. Any equitable rights which might have operated but for the *NOC Regulations* cannot be relied upon because: (a) the statute establishes a scheme for compensation and, as such, common law rights are excluded; and, (b) with irresistible clearness, Parliament intended to eliminate any claim to unjust enrichment.

[174] I find on this ground of argument that Apotex's claim for a disgorgement of the revenues or profits of Abbott and Takeda must fail in the circumstances of this case, for both the legal and factual reasons set out above. On this basis alone, I grant Abbott and Takeda the partial summary judgment they seek.

Are there juristic reasons for the enrichment of Abbott and Takeda?

[175] On its own, the foregoing analysis is sufficient for the Court to grant summary judgment dismissing Apotex's disgorgement claim. However, if I have erred in this analysis and in the event that it were to be determined that Parliament did *not* intend to exclude a claim to unjust enrichment, I would still find Apotex's claim to be untenable because the onus is on Apotex to satisfy all three elements of an alleged unjust enrichment cause of action, and it has not. Apotex must demonstrate that the facts of this case do not fall within one of the four established categories of juristic reason, only two of which are relevant here, namely contract or disposition of law. I accept the submissions of Apotex and Takeda that it cannot satisfy that tripartite test.

[176] Given the strength of the complete code argument, and the other reasons set out above why Apotex's claim for an unjust enrichment-based disgorgement remedy must be dismissed, my analysis relative to the existence of juristic reasons for the alleged enrichment is more summary in nature, and largely reflects the submissions to be found in the factums of the parties.

[177] Both Abbott and Takeda accept for the purposes of this analysis that the first two elements of an unjust enrichment cause of action are present here: (1) that Abbott and Takeda have been enriched; and, (2) that Apotex has experienced a corresponding deprivation. The question is, then, whether there is an absence of juristic reason for that enrichment. The onus is on Apotex to show that there is no such juristic reason present here. In my view, Apotex cannot discharge that burden. I agree with the submissions of the moving parties that as a matter of law,

there are two juristic reasons present for any alleged enrichment – the operation of the statutory provisions of the *NOC Regulations* and the September 2008 settlement agreement between the parties.

(i) Are the *NOC Regulations* a juristic reason for the enrichment?

[178] Two important decisions of the Supreme Court of Canada have concluded that validly enacted statutes or regulations will constitute a juristic reason for enrichment within the meaning of the third branch of the unjust enrichment test.

[179] In *Gladstone v. Canada (Attorney General)*,[71] the Department of Fisheries and Oceans had lawfully seized and sold herring spawn on kelp which the respondents had harvested allegedly in violation of the *Fisheries Act*.[72] The Crown held the proceeds pending the outcome of litigation. The respondents were aboriginal. They were convicted of offences under the Act but then the Supreme Court ordered a new trial. In 1996, the Crown stayed those proceedings and it then paid the net proceeds to the respondents, but similar to the decision in *Zaidan*, above, they claimed interest. The British Columbia Supreme Court dismissed that claim but the B.C. Court of Appeal reversed the decision, holding that in this case the Crown owed a fiduciary duty as an "administrator" to pay interest on the money. When the matter reached the Supreme Court, the decision of the trial judge was reinstated.

[180] The sections of the *Fisheries Act* under which Gladstone's property had been seized did not provide for the payment of interest on proceeds held by the Crown. As a result, Gladstone sought to rely on the doctrine of unjust enrichment to supplement the statute, but that claim was rejected on the basis that the *Fisheries Act* constituted a complete code dealing with the return of seized property and contained a comprehensive framework for dealing with issues that arose out of seizures. As such, even though it might have been considered unfair, the Supreme Court held that the plain meaning of the statute was clear. It imposed no obligation on the Crown to pay interest or any other amount in addition to refunding the proceeds from the sale of the seized fish spawn.

[181] There was argument before me about whether the juristic reason element of an unjust enrichment must be "required by law", or can it simply be a consequence of the operation of the law. On the *Apotex v. Abbott and Takeda* motion to strike pleadings that was heard before Justice Whitaker, he found that the "juristic reason" must be "required by law", but this is clearly at odds with the Supreme Court of Canada jurisprudence.

[182] There is no requirement that the invocation of the legislation be required by law. It is satisfactory if it is merely the operation of the law that produces the result. Contrary to Apotex's assertion at paragraph 63 of its factum, there is no need for an express authorization or requirement that Abbott keep those profits, which Apotex erroneously describes as having been earned at its expense. This point is confirmed in *Garland v. Consumers' Gas Company*,[73] where the Supreme Court held that if Ontario Energy Board orders were constitutionally valid and

---

[71] 2005 SCC 21, [2005] 1 S.C.R. 325.
[72] R.S.C. 1970, c. F-14.
[73] [1998] 3 S.C.R. 112.

operative, then they provided a juristic reason which barred recovery by Garland. Indeed, relative to the argument of Consumers' Gas that it was entitled to retain the late payment penalties obtained from its customers merely by reason of the Ontario Energy Board's rate orders which qualified as a disposition of law, the Supreme Court concluded that Consumers' did not need to have been required by law to collect the payment before it could retain it. In the Supreme Court's view, it was clear that the simple existence of valid legislation as in that case could provide a juristic reason which would bar restitutionary recovery.

[183] The *Patent Act* provides exclusive rights to the patentee, and sets out remedies, such as the two-year stay, for the enforcement of those rights. Parliament saw fit to enact the *NOC Regulations* pursuant to the *Patent Act* in order to prevent the infringement of patents and to provide remedies in addition to those available under the act itself. Abbott and Takeda took the position that Abbott's commencement of proceedings to protect its patent rights ought to be considered a juristic reason to retain any benefit that it is alleged to have received, and that the regulations themselves permit the consequences they do. Those consequences may include the earning of higher revenues or profits by innovators during the stay period mandated under the legislative framework while generic manufacturers were legislatively denied market access.

[184] There are two final points I would note in regards to my conclusion that the *NOC Regulations* do provide a juristic reason for the deprivation that Apotex complains of. The first is that Apotex and other generics themselves clearly benefit from the operation of the *Patent Act* to the extent that they rely upon the "early working" and "stockpiling" provisions of the regulations. Takeda makes the point in its factum that this has allowed generic manufacturers to accelerate the market entry of their generic products in Canada by some 3 to 5 years. As such, *that* balance that is in *favour* of the generic manufacturers must also be taken into account while taking care to ensure not to upset the legislative balance struck by Parliament in creating this statutory framework. To the extent that Apotex has already benefited from the framework, it would be contrary to that balance, in my view, to additionally permit it to claim disgorgement of the innovators' revenues or profits based on principles of unjust enrichment, at least in the absence of an independent cause of action founded on the presence of recognized elements of egregious conduct that constitute a tort.

[185] It is curious to note, as Takeda argues at paragraph 64 of its factum, that if Apotex's claim for unjust enrichment were to be granted, it would permit Apotex to have a windfall that it could never have received had the *NOC Regulations* not been invoked. That follows because those regulations do not provide for the return of amounts beyond the losses incurred by the generic manufacturer on its own. Thus, any amounts that Abbott or Takeda may have obtained beyond the actual losses incurred by Apotex as calculated under s. 8 of the regulations must be considered to be "ancillary" or "incidental" to the operation of those regulations. That in turn provides a juristic reason for the retention of those amounts.[74]

[186] Finally on this point, I accept the submissions of Abbott and Takeda that there is no corresponding law or jurisprudence that can provide any support to the proposition that a generic

---

[74] See: *Apotex Inc. v. Merck & Co.*, 2009 FCA 187, at paras.89-91; *Apotex Inc. v. Eli Lilly Canada Inc.*, 2011 FCA 358, at para. 23; *Gladstone v. Canada (Attorney General)*, at paras. 19 and 22; s. 8 of the *NOC Regulations*.

manufacturer, such as Apotex, can be entitled to expropriate an innovator's revenues or profits based on proceedings commenced by the innovator under the *NOC Regulations*.

(ii) Is the settlement agreement a juristic reason for the enrichment?

[187] In *Rathwell v. Rathwell*,[75] the Supreme Court recognized that a contract providing for the enrichment of one party to the corresponding deprivation of the other could constitute a "juristic reason" for that enrichment and prevent the three elements necessary in a claim for unjust enrichment from being satisfied.

[188] The relevant terms of the agreement entered into between the parties on September 11, 2008 are reviewed above. Importantly, Apotex agreed that it would not commence sales of Lansoprazole until May 1, 2009, and in doing so, it agreed that Abbott and Takeda would continue to enjoy market exclusivity, and the profits that went with it, for another eight months. For its part, Abbott and Takeda agreed to discontinue all of their pending applications against Apotex, and to allow or permit Apotex to enter their market before the expiry of the '741 patent. The parties also agreed that Apotex would be permitted to retain the right to claim damages under section 8 of *NOC Regulations* for the limited period of April 1, 2007 through May 1, 2009. Against those facts, it is incomprehensible to me that Apotex now claims that the alleged unjust enrichment of the moving parties could result from the settlement of a contract that Apotex entered into freely, for good and valid consideration.

[189] In its factum, Abbott includes a fitting quote on point from Professor Birks' text, *An Introduction to the Law of Restitution.* The rationale for the legal position is set out at pages 46 to 47:[76]

> ... there has to be a rule of the effect that, at least unless and until the contract is prematurely discharged by frustration or in reaction to a repudiatory breach, the plaintiff can never put himself in a better position by suing in unjust enrichment rather than in contract. Otherwise the law of restitution would subvert bargains. You repair my windows up the price which, after the bargain has been struck, turns out to be below the going rate. If you could subsequently improve your position by switching to a claim in free acceptance my bargain would be spoiled. And the courts would at a stroke have accepted the task of regulating the whole business of economic exchange.

I accept the position put forward by Abbott and Takeda that that is exactly the case the court is faced with here.

[190] At the point in time when Justice Phelan's decision was under review, when Novopharm had just lost its case in the Federal Court, and after Parliament had amended s. 8 to eliminate any

---

[75] [1978] 2 S.C.R. 436, at p. 445 (in dissent), adopted in *Pettkus v. Becker*. See also: *Peter v. Beblow*, at p. 987; *Garland v. Consumers' Gas*, at paras. 44-46; *Apotex Inc. v. Eli Lilly Canada Inc.*, 2011 FCA 358, at para 23.

[76] P. Birks, *An Introduction to the Law of Restitution* (Oxford, England: Clarendon Press, 1985), at pp. 46-47, cited with approval by the Alberta Court of Appeal in *Luscar Ltd v. Pembina Resources Ltd.*, [1995] 2 W.W.R. 153.

reference to profits, these parties, including Apotex, consensually settled the litigation that was ongoing between them relative to Lansoprazole and the '741 patent.

[191] By commencing this action and taking other steps, Apotex appears to have honoured certain of the provisions of that agreement more in breach than in observance. Nevertheless, a negotiated solution to that litigation occurred under which Abbott and Takeda continued to have market exclusivity for eight additional months, and Apotex got onto the market eight months before the patent would otherwise have expired and it could otherwise have accessed the marketplace.

[192] In the course of negotiating that contract, Apotex negotiated the right to claim damages under s. 8 of the *NOC Regulations*, not only for the period up to the discontinuance of the action, but also for an additional eight months. I note that the additional eight months is subject to any defences that might otherwise be available to Abbott and Takeda, which could of course include the fact that it turned out that Apotex had not received a NOC from the Minister at that time in any event, and thus had no statutory entitlement to s. 8 damages for part of that period whatsoever.

[193] By coming to this court with these claims, not only does Apotex seek to circumvent determinations that have already been made by the Federal Court that would seem plainly to bind it, thus leaving itself open to an allegation that it is engaging in forum shopping,[77] but as well, after entering into a contract for good and valid consideration it has chosen to ignore that contract. It seeks to improve its bargain relative to the damages to which it would otherwise be contractually entitled under s. 8 by the advancement of an unjust enrichment based disgorgement of profits claim brought before the Superior Court of this province.

[194] Abbott refers at paragraph 92 of its factum to a long line of judicial authority that supports the proposition that the presence of a valid contract between the parties that provides for a benefit to one party at the expense of the other does constitute a juristic reason for the arrangement, and as such, precludes a claim of unjust enrichment relative to that benefit.[78] Settlement agreements have similarly been held to constitute a juristic reason for the possibility of an alleged unjust enrichment.[79] I find that the settlement contract between these parties so qualifies and is a valid juristic reason. As such, Apotex has failed on both fronts to establish the absence of a juristic reason for the enrichment and deprivation. I would dismiss its claim for unjust enrichment even if I had not found that it is precluded from obtaining that remedy by the clear and inescapable words of the *NOC Regulations*.

---

[77] See: *Oberlander v. Canada (Attorney General)*, [2004] O.J. No. 1574, at para. 9 (S.C.J.); *Mignacca v. Merck Frosst Canada Ltd.* (2009), 95 O.R. (3d) 269 (Div. Ct.), at paras. 85-86.

[78] See: *337965 B.C. Ltd. v. Tackama Forest Products Ltd.* (1992), 91 D.L.R. (4th) 129, at p. 182 (B.C.C.A.); *Canadian Imperial Bank of Commerce v. Melnitzer (Trustee of)* (1993), 1 E.T.R. (2d) 1, at paras. 102-105 (Ont. S.C.J. [In Bankruptcy and Insolvency]); *Canada (Attorney General) v. Confederation Life Insurance Co.* (1995), 24 O.R. (3d) 717, at pp. 771-72 and 779-80 (Gen. Div.); *Windisman v. Toronto College Park Ltd.* (1996), 28 O.R. (3d) 29, at paras. 52-53 (Gen. Div.); *Rillford Investments Ltd. v. Gravure International Capital Corp.*, [1997] 7 W.W.R. 534, at paras. 29-31 (Man. C.A.); *Pak v. Reliance Resources Group Canada Inc.*, [2002] O.J. No. 684 (S.C.J.).

[79] See: *Brent v. Slegg Construction Materials Ltd.*, 2007 BCSC 661, [2007] B.C.J. No. 1005, at para. 44.

The impact of the recent *Teva* and *Apotex v. Pfizer Ireland* decisions

[195] Finally, as noted above, I wrote to each of the parties to this litigation on November 27, 2012, while this decision was under reserve. I requested that they make brief written submissions to me by December 19, 2012, relative to the impact, if any, on the outstanding motion for summary judgment in this proceeding of Justice Zinn's November 8, 2012, decision in a summary judgment motion brought in Federal Court in *Apotex v. Pfizer Ireland.* In that litigation, the generic manufacturers, Teva and Apotex, had separately commenced actions challenging Pfizer's patent for Viagra, albeit by different routes.

[196] Apotex had previously tried to gain access to the generic market to produce a generic version of Viagra by addressing Pfizer's patent under the *NOC Regulations*. It served Pfizer with a NOA alleging that Pfizer's patent was invalid. Pfizer invoked its rights under those regulations and sought an order of prohibition precluding the Minister from issuing a NOC to Apotex for the generic Viagra product. At the Federal Court, Apotex's allegations were found not to be justified and the court granted the prohibition order sought by Pfizer. Apotex unsuccessfully appealed that decision. Then Apotex brought an impeachment action, as in this case, outside of the *NOC Regulations*.

[197] Teva is another generic manufacturer who also had an interest in accessing the market to sell its generic version of Viagra. Its litigation took the same route as Apotex with the same results, except it was in the context of an application under the *NOC Regulations*, rather than an action for impeachment. However, it also ended in having its allegations of patent invalidity thrown out by the Federal Court, It sought and was granted leave to appeal to the Supreme Court of Canada.

[198] The Supreme Court agreed with Teva's allegation. It found that Pfizer had obscured the true invention and thus had failed to comply with s. 27(3) of the *Patent Act*, which requires that an innovator disclose the invention in clear terms. As a result the appeal was granted and the patent for Viagra was declared void.[80]

[199] After the release of its decision by the Supreme Court, Apotex immediately brought a motion for summary judgment against Pfizer in its litigation and that motion was heard by Justice Zinn.

[200] Even though the two actions proceeded using different procedure, Justice Zinn found that "the determination that the '446 patent (Viagra) fails to meet the requirement of sufficient disclosure... is a legal determination binding on this court and is dispositive of Apotex's claim." He concluded that there could be no genuine issue for trial, because no result was possible other than a finding that the Viagra patent was invalid.

---

[80] For the sake of completeness, I should note that this case arose from a proceeding under the *NOC Regulations* and thus there is some dispute as to whether the Supreme Court of Canada had the jurisdiction to issue the remedy that it did as a technical matter. Many in the patent and trademark bar were of the view that it only had jurisdiction to declare that Teva's allegation was justified. Pfizer does not contest the Supreme Court's finding that Teva was successful and is entitled to market entry, but it has brought a motion to request that the Supreme Court correct what it claims to be a technical deficiency. Others say it does not matter. The fact is the Supreme Court struck down the Viagra patent and whatever consequences ought to will flow from that finding.

[201] I asked for the submissions of counsel in this matter because like this case, the motion before Justice Zinn was a summary judgment motion brought soon after the Supreme Court of Canada decided the question in *Teva*. It struck me then, as it does now, albeit with perhaps not quite as much force, that the circumstances in this case are not dissimilar to the circumstances in that case. In that case, a determination had been made by the Supreme Court of Canada which clearly and finally determined, whatever the technicalities, that the Viagra patent was void and invalid. As such there was no basis upon which Apotex's motion for summary judgment could not be granted.

[202] The circumstance is somewhat different in this case, in that the Supreme Court did not overturn or specifically uphold the decision of the Federal Court of Appeal in *Eli Lilly*, but simply denied leave to appeal to Apotex from that strong and comprehensive decision.

[203] Abbott and Takeda take the position that Justice Zinn's decision overwhelmingly supports the appropriateness of granting summary judgment in this case. Apotex, however, says that this summary judgment motion differs significantly from what was before Justice Zinn, and that there is no binding or dispositive decision in this case which this court is bound to follow, unlike in that case. I disagree. In my view, Justice Zinn's decision and the circumstances in which it arose cannot help but be regarded as strongly supportive of the motion for summary judgment brought in this case by Abbott and Takeda.

[204] The Supreme Court's underlying findings relative to the '446 Viagra patent was one of insufficiency which constitutes a "determination of law". Justice Zinn made particular note of this point in finding that the underlying determination made by the Supreme Court was a legal determination adequate for him to ground the summary judgment he granted there to Apotex.

[205] That decision is helpful because it demonstrates that summary judgment is appropriate on questions of law, particularly in a case like this, where there is strong authority to support the decision. In this case, this court is asked to make a legal determination. It is asked to determine whether Apotex can claim Abbott and Takeda's profits by way of an unjust enrichment remedy in the absence of any facts other than those presented in support of its claim for damages under the *NOC Regulations*. Apotex plainly admits in its factum that that is a question of law.

[206] The decision is also helpful insofar as it emphasizes and underscores the position of the moving parties that summary judgment is appropriate in a case like this where the Court has before it all of the information necessary to determine these issues now, without material facts being in dispute, and with a trial judge not being in a potentially better position to decide these issues. Indeed, the issues are pure questions of law and the forceful and inescapable answers provided by the jurisprudential landscape, plainly shows that they ought to be answered now.

[207] There is strong appellate authority in this case which squarely addresses the questions upon which Abbott and Takeda seek summary judgment. The Federal Court of Appeal has conclusively held that the very claim brought by Apotex for unjust enrichment is untenable and cannot succeed as a matter of law, and the Supreme Court of Canada has denied leave to appeal from that decision.

[208] It may be true that the decision of the Federal Court of Appeal is not binding on this court, despite leave having been refused by the Supreme Court of Canada, but plainly the Federal Court of Appeal's decision on this question of law provides persuasive authority that can serve as the foundation for this court to grant summary judgment and dismiss Apotex's claim for unjust enrichment.

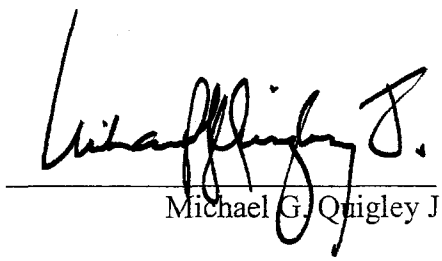
[209] It is the only decision in any court to directly and substantially consider and resolve the question of law that is at issue in the present case before this court. Thus, while not formally binding, the doctrine of judicial comity calls for it to be followed in order to prevent the same legal issue from being decided differently by different courts. Judicial comity seeks to promote certainty in the law. It seeks to avoid the disparate potential results of forum shopping that can arise by picking and choosing what courts to bring actions in. Takeda and Abbott emphasize that this aspect of the issue is critical to avoid the ability of the generic manufacturers to try to avoid or circumvent the developed and developing Federal Court jurisprudence which has consistently rejected their position. As such, and to avoid such fissures in the development of the law, departures from the principle of judicial comity should be rare and only occur where the court is convinced that the prior decision is wrong and is capable of advancing cogent reasons to support that view.

[210] I accept the submissions of the moving parties relative to this particular issue, as I have on the summary judgment motion as a whole, that following the Federal Court of Appeals decision in *Eli Lilly* is not only consistent with Justice Zinn's approach in *Apotex v. Pfizer*, where presumably Apotex argued the other side of this same coin, but it also serves the interests of justice by avoiding divergent judicial pronouncements on identical legal issues.

[211] There is no genuine issue for trial here. In that case, the result went in Apotex's favour. But here the opposite result must obtain. The only possible result here is a finding that Apotex's claim to the profits of Abbott and Takeda based on principles of unjust enrichment, cannot be granted and must be dismissed with costs.

Conclusion

[212] The motion for partial summary judgment brought by Abbott and Takeda against Apotex is granted. An order for partial summary judgment shall go in the form sought in the amended notice of motion. If the parties are unable to settle the order on that basis or otherwise, acting reasonably, they may contact the court for further directions. If the parties are unable to resolve the question of costs between themselves, acting reasonably, they may contact the court for further directions. I wish to express my gratitude to all counsel for the thoroughness and creativity of their arguments, and the breadth of helpful authority they put before the court.



Michael G. Quigley J.

Released: January 15, 2013

CITATION: Apotex Inc. v. Abbott Laboratories Limited, 2013 ONSC 356
COURT FILE NO.: CV-09-391938
DATE: 20130115

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:

APOTEX INC.

Plaintiff/Responding Party

- and –

ABBOTT LABORATORIES, LIMITED, TAKEDA PHARMACEUTICALS COMPANY LIMITED, and TAKEDA PHARMACEUTICALS AMERICA, INC.

Defendants/Moving Parties

REASONS FOR JUDGMENT

Michael G. Quigley J.

Released: January 15, 2013